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.

NCEPOD

Improving the quality of healthcare

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.

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Foreword

This study of the care provided to children, teenagers and young adults receiving systemic anti-cancer therapy (SACT) – or chemotherapy as it is more commonly known – follows a similar study in adult patients 'For Better, For Worse' that NCEPOD published in 2008.[1]

When I re-read the foreword to that report, written by Professor Tom Treasure, Chair of NCEPOD at that time, I found myself reflecting on the statement that said *" Patients have an inherent desire to trust their doctor and to believe that something positive might happen; most doctors have a compelling desire to not distress their patients. These factors together can lead to some unfortunate management decisions, resulting in 'doing something'…"* It strikes me that this could so easily be the summary to this report as well. Indeed, it is not altogether surprising, since the problems that stem from the inherent desire to carry on treating are probably exacerbated in such a young group of patients, coupled with the ever changing landscape of cancer treatments, demographics and expectations.

This report covers an emotive subject, and the findings in the report have been presented with appropriate caution. It is not our role to discuss the rights and wrongs of individual situations, but to bring together clinical expertise to comment on the care that has been provided in the sample of cases that were reviewed. Our second strength is to formulate recommendations for how clinicians might improve the quality of care for their future patients. As in all NCEPOD studies, the reviewers' opinions were based on what was recorded in the clinical notes. It may be the case that some key discussions did indeed take place but were not documented, which in itself offers an opportunity for improvement.

The study sample does not reflect the whole population of young people receiving cancer treatment. 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. However, we deliberately selected a group of patients who had died or gone to critical care within 60 days of receiving SACT. In short, these young people were extremely unwell, and for many of them a poor outcome was probably expected, which is why the care around their final treatment was important to review. One might have expected that these 'worst case' care scenarios would be the very cases in which the most careful review would take place. However, it was in this group that an holistic assessment of the appropriateness of SACT was often lacking.

Some readers of this report may be surprised that such a review of clinical practice is needed in 2018. That clinicians in this field felt there was more that could be done to improve the care they provide is reassuring. Furthermore, this report is not intended as a criticism of cancer care for children and young adults across the UK, indeed we identified that there are many areas of good practice. However, it does act as a reminder that we cannot afford to become complacent and must constantly strive to empower clinicians to develop processes that mandate multidisciplinary input into the making of challenging decisions.

Let me finish by noting that the 2008 study reported that the data returns had been lower than previous NCEPOD studies, and that there had been a lack of willingness by some clinicians to have their practice scrutinised. I am pleased to say that this was not considered to be such a problem with the current study, but it did get off to a very slow start, and has run late to publication because of it. The delay occurred in identifying patients for inclusion. Many hospitals did not keep electronic links between who had received SACT and their outcome, with many prescriptions on separate, often paper- based systems. Since starting the study the requirement for electronic prescribing has become mandatory in England, and we have been assured that the timing of data collection was simply unfortunate. We should use this report as an opportunity to highlight this previous

failing to all those involved with overseeing this process in the future. Not being able to identify the outcome of a patient following chemotherapy is simply not acceptable.

As with all NCEPOD publications I would like to thank the many individuals who have contributed to the production of this report. The study proposer, the NCEPOD Steering Group who represent the Royal Colleges, their Faculties and Specialist Associations for identifying the clinical need and short listing the topic. The multidisciplinary study advisory group and patient representatives for guiding us as to what we should be looking for and the questions we needed to ask. The reviewers who generously gave up so much of their time to painstakingly review each case and the clinicians who took the time to complete questionnaires. The NCEPOD Local Reporters for identifying the cases and for copying the notes for us. The NCEPOD Ambassadors who championed the topic locally. I would also like to thank the lead authors for writing such a detailed report, and the researchers for their analysis and guidance on interpreting the data, the wider NCEPOD team for running the study and our panel of lay representatives for their invaluable insight and non-clinical interpretation of the findings. Finally, thank you to my fellow Trustees and our clinical co-ordinators for all their support.

Professor Lesley Regan
NCEPOD Chair

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'*.[5] 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.[6] 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.

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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 61-64.

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)

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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. 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.

The assessment of patients before the administration of SACT was variable - essential investigations were done in almost all patients but evaluation of disease response, previous toxicity and holistic review of the patient's fitness to receive SACT (performance status) was only performed in half (61/123; 49.6%) 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.

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Method and Data Returns

Study advisory group

A multidisciplinary group of clinicians comprising consultants from paediatric, adult and teenage 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 1st June 2014 and 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 who present in an emergency with complications of 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, POSCU 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 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.

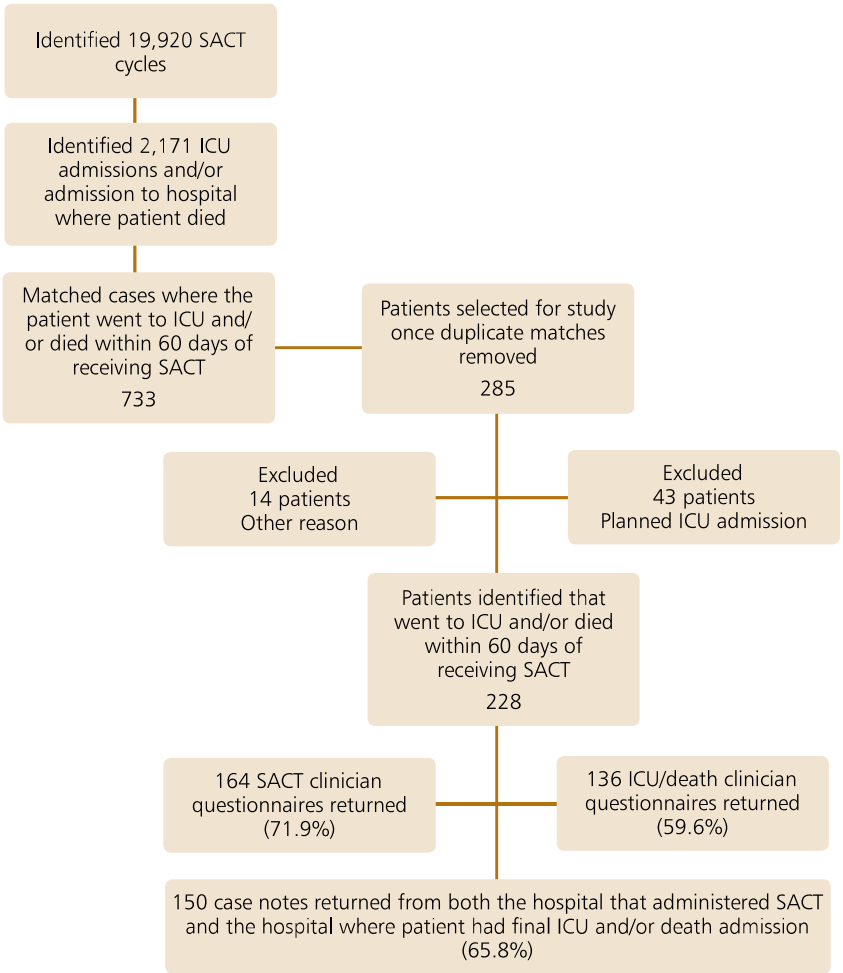

Figure 1.1 Data returns

2

Organisation of services

Delivery of systemic anti-cancer therapy

All hospitals in the UK where either systemic anti-cancer therapy (SACT) is delivered or children, teenagers and young adults with cancer were admitted acutely, were sent an organisational questionnaire to complete, with the aim of identifying the resources available and processes in place in those hospitals. A completed organisational questionnaire was received from 165 hospitals.

The 1995 Calman–Hine plan outlined radical reform of the UK's cancer services. Its main recommendation was to concentrate care into the hands of site-specialist, multidisciplinary teams. The report identified that a network of centres providing paediatric oncology existed and promoted the further integration of services. The report urged purchasers to look for opportunities to develop services for adolescents.[7]

National guidelines published by NICE in 2005 *'Improving Outcomes Guidance for Children and Young People with Cancer'*[8] required that age appropriate, safe and effective services should be delivered as locally as possible.[9] Specialised care is therefore centralised in principal treatment centres (PTCs) for children's cancer to ensure depth and breadth of cancer coverage; specialist clinical support; and age appropriate care across the age range. The PTC retains overall responsibility for the cancer treatment plan but components of care may be delivered in designated paediatric oncology shared care units (POSCUs). These units commonly sit within hospitals outside the centre. Three levels of care have been defined for a POSCU in terms of what types of clinical activity may be undertaken with the corresponding requirements for staff and facilities. The measures for a given POSCU will be determined therefore by the Level (1, 2 or 3) which is agreed for that POSCU between it, the PTC and the commissioners.[10] The care "Level" of a POSCU determines the highest level of services which it should offer. It may (and probably will) offer services at levels lower than its agreed level. If the POSCU is agreed as being allowed to offer services at a given level it is then required to have at least the minimum supporting infrastructure (staff and facilities) corresponding to that Level. (POSCU Levels are detailed in Appendix 1)

The category of hospital delivering SACT to children, teenagers and young adults is shown in Figure 2.1 overleaf. PTCs were centred in University Teaching Hospitals (UTH) and Specialist Children's Hospitals (SChH). POSCUs were distributed throughout all hospital types including District General Hospitals (DGHs) and Specialist Cancer Hospitals (SCaH). (Of note was that two teenager and young adult (TYA) centres were situated in SChHs).

Figure 2.2 overleaf, shows the number of hospitals in each category with beds available to paediatric (0-16) patients and TYA (17-24) patients. It is a requirement that Level 1 POSCUs have inpatient supportive care including care of children with febrile neutropaenia.

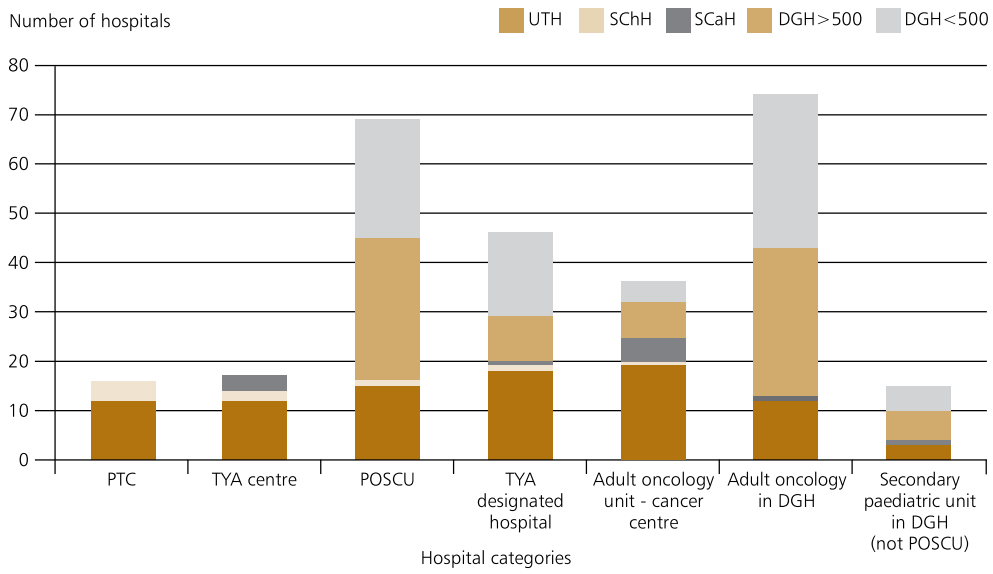

Figure 2.1 Hospital categories regarding specialties

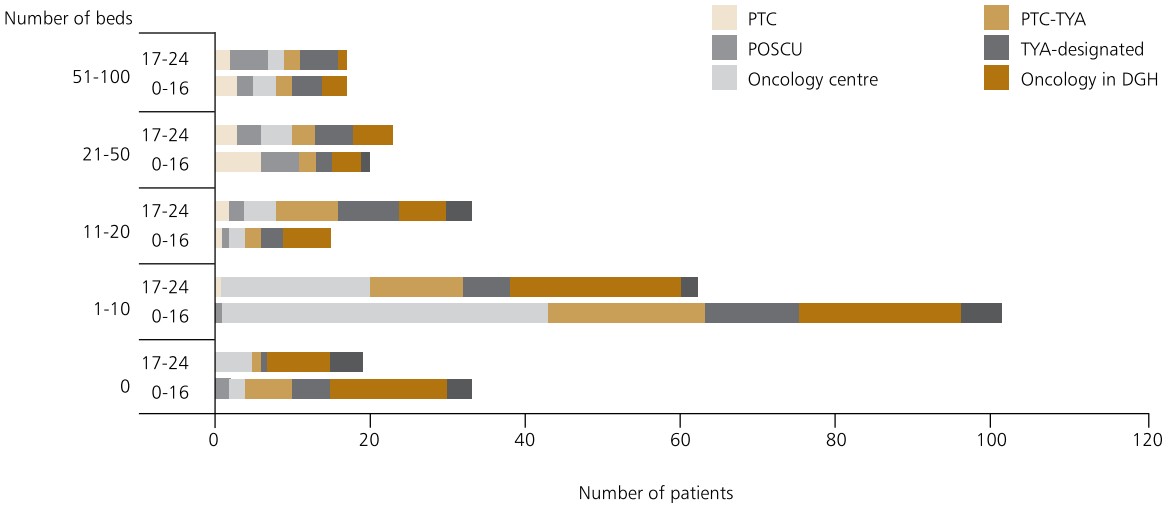

Figure 2.2 Numbers of beds for paediatric (0-16 years) and TYA (17-24 years) patients in each hospital category

Figure 2.3 shows the type of hospital where SACT was provided, displayed by the age range of the patients.

Figure 2.4 shows where critical care support was available. One adult Critical Care Unit (CCU) would admit patients in the 0 – 11 age range.

Of the 19 PTCs for children in the UK 17 responded and 15 reported an on-site paediatric intensive care unit (PICU). It is expected in England, at least, that PTCs should have access to age appropriate, co-located critical care support.[11]

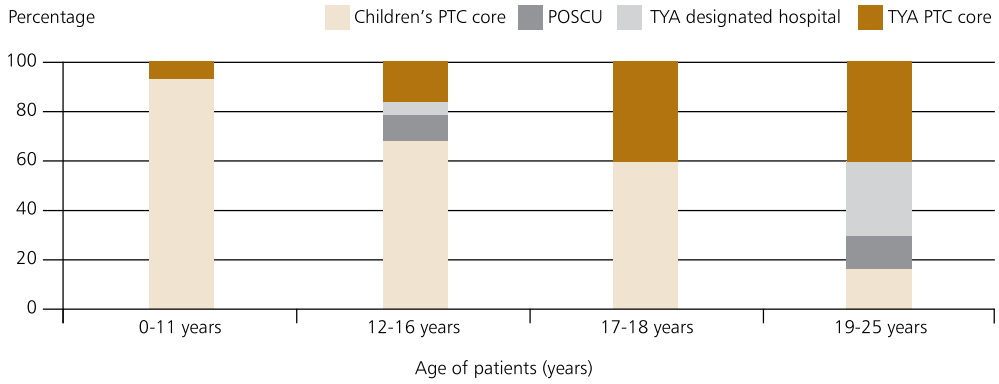

Figure 2.3 Age of patients in the study and types of hospitals where SACT is provided

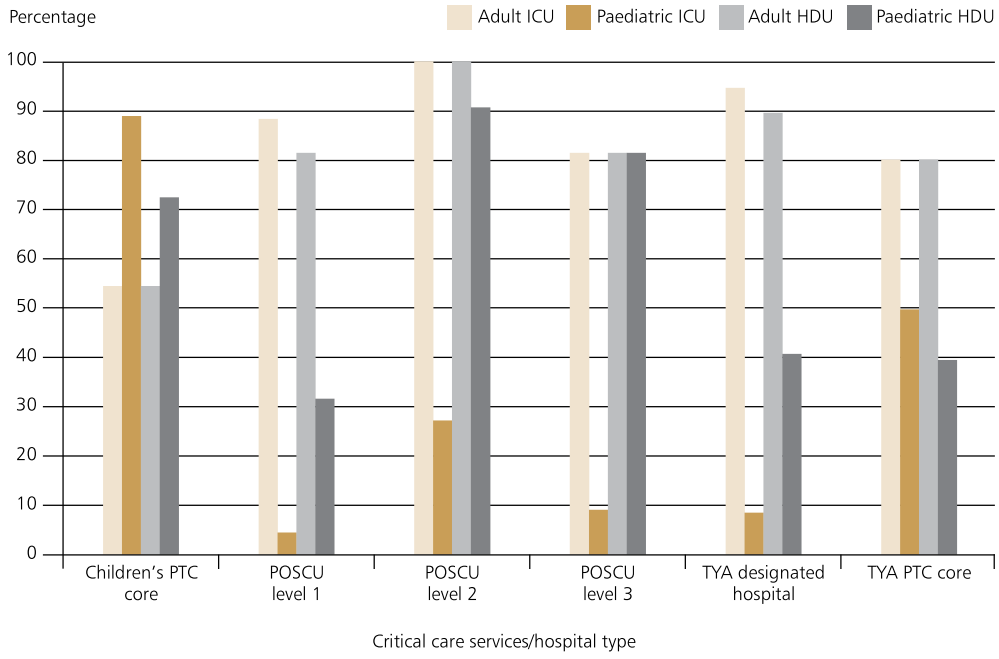

Figure 2.4 Critical care services provided by hospital type

This was of particular note as these centres would be administering toxic therapy with an expectation that some patients would require intensive care to deal with the side effects. The low percentage of Level 3 POSCUs with paediatric critical care was not necessarily a surprise given that paediatric critical care tends to be centralised in a small number of units that are usually located within the local children's hospital. However, the fact that only 9/11 Level 3 POSCUs from which a response was received had a paediatric high dependency unit (HDU), was of note given the fact that they would admit acutely unwell children with complications of SACT. However, paediatric HDU is not a requirement for Level 3 POSCUs, they only require a paediatric anaesthetic service.

The provision of pain and palliative care by age group and hospital type is shown in Figure 2.5

These self-reported organisational figures show that there appeared to be broad provision of acute pain services and palliative care in both children's PTC and TYA PTC.

Table 2.1 Route of admission to hospital

	Number of hospitals
Via the emergency department	59
Direct to ward	86
Other	25

Answers may be multiple; n=115

The route of emergency admission for patients undergoing SACT is shown in Table 2.1. The 25 'others' included outpatients, 24-hour helpline and an assessment unit.

Patients were reported to be admitted as emergencies to a general ward (adult), general paediatric ward (if patient age appropriate, oncology ward (adult), general TYA ward (if patient age appropriate), oncology paediatric ward (if patient age appropriate) or an oncology TYA ward (if patient age appropriate).

The distance from home to hospital is of importance in the management of complications of SACT, particularly the early administration of antibiotics in patients with neutropaenic sepsis, as journey times will affect time to antibiotic administration. Despite this, maximum journey times for patients travelling to the hospitals was reported to exceed an hour by almost a quarter of hospitals (Table 2.2).

Table 2.2 Maximum journey time to this hospital

	Number of hospitals	%
30 minutes	31	26.7
1 hour	58	50.0
>1 hour	27	23.3
Subtotal	**116**	
Not answered	3	
Total	**119**	

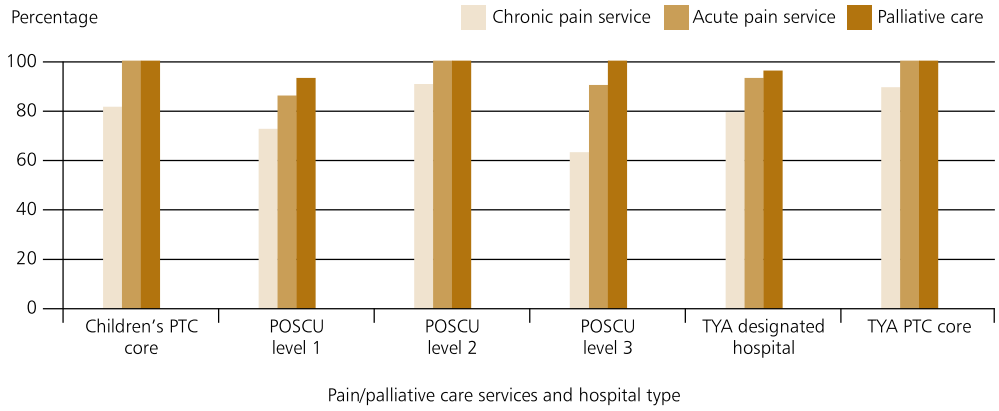

Figure 2.5 Pain and palliative care services by hospital type

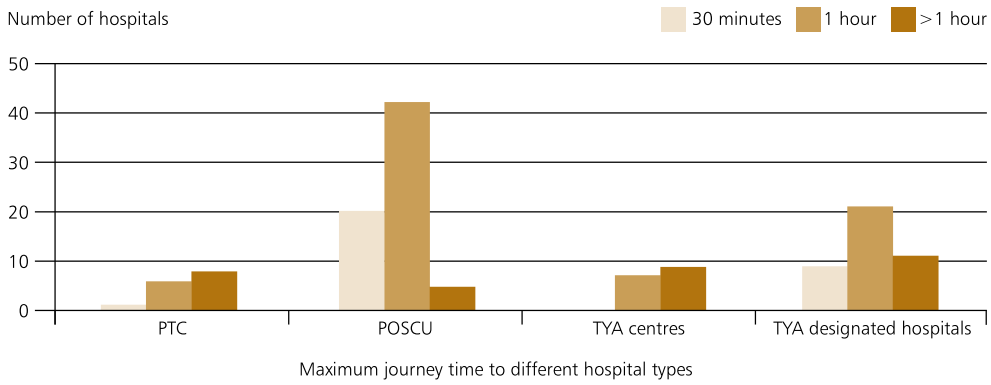

Figure 2.6 Maximum journey time to different hospital types

In general, networks of care improve communication which promotes good care. Seven of the 149 hospitals from which an organisational questionnaire was received, were not part of a specific cancer network. However, there is ongoing work to develop Cancer Alliances across the UK.[12]

Management of SACT

In England, all NHS Trusts and NHS Foundation Trusts providing cancer SACT services are required to submit monthly data downloads to an agreed timetable, one month in arrears. These data must represent all treatment activity in the month period, including SACT drug regimens started and completed or ceased in that time period. The data repository is hosted by the National Cancer Registration and Analysis Service (NCRAS) Oxford.[13] Furthermore, in 2016, NHS England produced a document mandating electronic prescription for SACT with full compliance expected by March 2017.[14]

The study period (March 2014 to May 2016) predates the document mandating electronic prescription of SACT but, the data supplied shows that electronic prescribing was not used universally at this time. For parenteral prescriptions, of the 30 hospitals that did not use electronic prescribing, 25/30 were hospitals in England. For oral prescriptions of the 32 hospitals that did not use electronic prescribing, 29 were in England.

The format of SACT prescriptions is shown in Table 2.3.

All hospitals should maintain a list of doctors authorised to prescribe both the first and subsequent cycles of SACT. There were 31/131 (23.7%) hospitals which were reported not to keep a list of those authorised to prescribe the first cycle of SACT and 23/131 (17.6%) failed to keep a list of those who could prescribe subsequent cycles.

Table 2.3 Format of SACT prescriptions

	Parenteral	%	Oral	%
Hand written only	8	7.0	10	8.6
Pre-printed / handwritten	22	19.1	22	19.0
Electronic	85	73.9	84	72.4
Subtotal	**115**		**116**	
Not answered	16		15	
Total	**131**		**131**	

Several levels of competency in prescribing SACT are described and doctors in specialist training (trainees) will only be permitted to prescribe under appropriate supervision within their competency level. Progress to the next level of competency requires that trainees are assessed as competent by an appropriate supervisor having demonstrated the required knowledge, skills and behaviours.[15] In this study 15 hospitals reported that doctors of grades ST3 and below were listed as being able to initiate SACT (Table 2.4).

Table 2.4 Staff grades authorised to initiate or prescribe SACT

	Listed grade - initiator of SACT	Listed grade - prescriber of SACT
Consultant	95	93
Associate specialist	23	20
Clinical fellow	3	16
Clinical assistant	1	13
Staff grade	10	35
ST3 and below	15	70

Answers may be multiple; n=100

In 49/115 (42.6%) hospitals non-medical staff could prescribe SACT. The staff that could do so included Clinical Nurse Specialists, Advanced Nurse Practitioners and Pharmacists. The types of SACT that may be prescribed by non-medical staff are listed in Table 2.5. Standard Operating Procedures (SOPs) were available to these groups in 45/49 hospitals.

Table 2.5 Types of SACT that can be prescribed by non-clinicians

	Number of hospitals
IV bolus SACT	20
Infusion SACT	17
Other oral SACT	34
Continuation therapy for all acute lymphoblastic leukaemias	11

Answers may be multiple; n=40

Competence to prescribe SACT is paramount. To achieve competence, training and evaluation of competencies should be undertaken. Figures 2.7 and 2.8 show the different groups of prescribers and their training and assessment status.

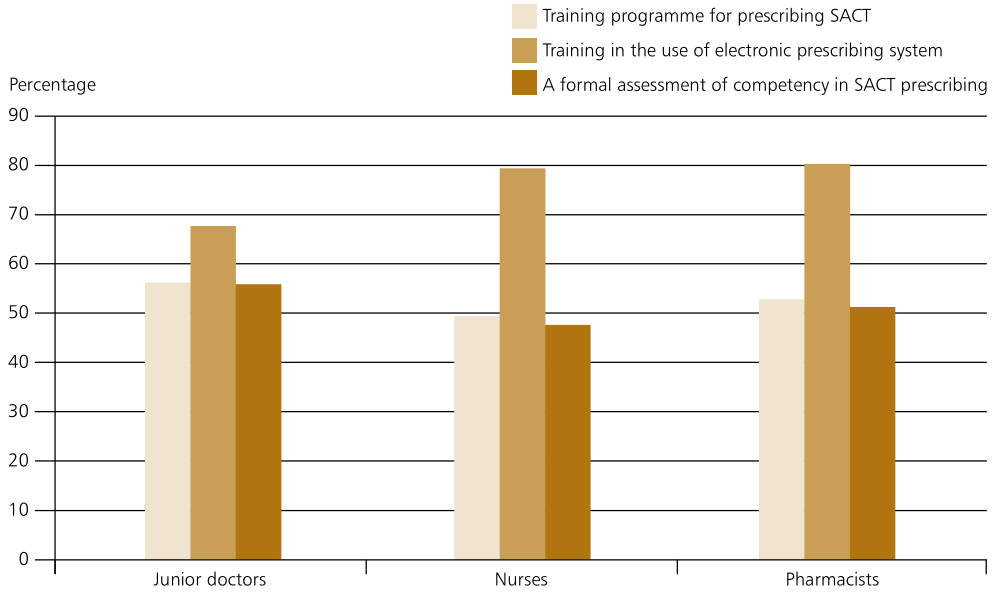

Figure 2.7 Training for staff in SACT prescribing

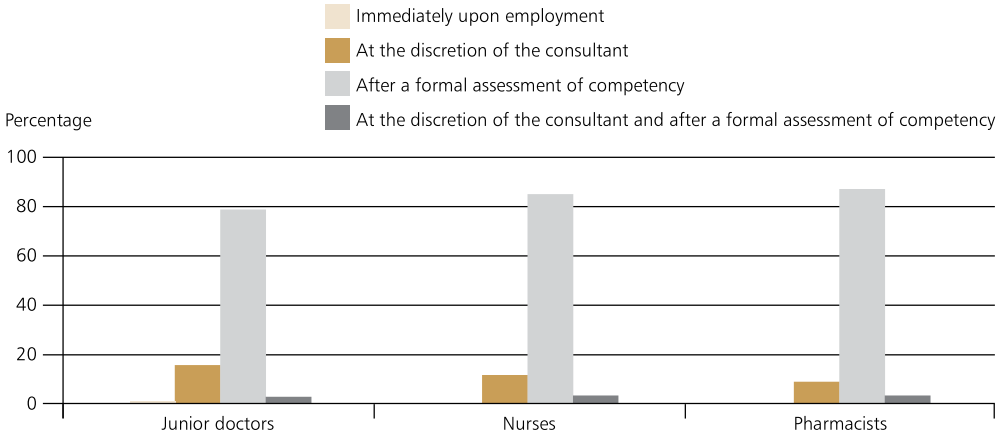

Figure 2.8 Point in training staff were allowed to prescribe SACT

Of those hospitals with policies for the dispensing of SACT, 60/112 (53.6%) had a formal policy that pharmacist-prescribed SACT should be checked by a second pharmacist. There were no formal training programmes for pharmacists to prescribe SACT in 43/91 hospitals (47.3%), or in the use of electronic prescribing systems in 19/97 (19.6%).

Of those hospitals where there was training for staff to prescribe SACT, Figure 2.8 shows the point in training that staff were allowed to prescribe SACT.

Pre-assessment prior to SACT

An important part of the administration of SACT is patient pre-assessment prior to the administration of SACT. From the data available 55/131 (42%) hospitals reported that an holistic assessment of the physical status of patients before administering SACT was not routinely performed. Table 2.6 shows the checks routinely made before administering SACT.

Table 2.6 Hospital policy that staff must routinely check the following before administering SACT

	Number of hospitals	%
Dose	118	90.1
Critical tests (blood tests)	115	87.8
Performance status	76	58.0
If performance status, this was assessed using a score	41	53.9

Answers may be multiple; n=131

In those hospitals where performance status before administering SACT was routinely checked, the performance scales used were listed as Lansky/Karnofsky, World Health Organisation (WHO), Eastern Cooperative Oncology Group (ECOG) and clinical assessment (see glossary on p67 for definitions).

Consent

Informed consent to any treatment requires that the patient (and or their legal guardian as appropriate) be fully informed. Patients receiving SACT need information on the treatment, in an easily understood format, covering the possible benefits and side-effects. Table 2.7 shows the ways in which patients were given information. In 2017, information on how to access audio-visual transmission via any number of digital media would have been expected, in addition to written formats. Only 34/130 hospitals were using audio-visual sources to transmit information to patients.

Table 2.7 Information given to patients

	Number of hospitals	%
Verbally in clinic	118	90.8
Patient info leaflets - general info on SACT	115	88.5
Patient info leaflets - booklets on specific tumour sites	106	81.5
Patient info leaflets-info specific to particular SACT regimens	108	83.1
Audio-visual patient information	34	26.2
Other	22	16.9

Answers may be multiple; n=130

Protocols help improve the quality of patient care and 101/119 (84.9%) hospitals reported having treatment protocols freely available on the hospital computer system (Table 2.8). Staff should be trained on how to access treatment protocols at the time of their induction and this information should be included in their induction pack.

Table 2.8 Location of local SACT protocols stored in hospital

	Number of hospitals	%
Hospital computer system/ intranet	101	84.9
Ward areas	42	35.3
Chemotherapy clinic	30	25.2
Outpatient department	26	21.8
On-site library	9	7.6
Included in oncology staff induction pack	4	3.4
Other	24	20.2

Answers may be multiple; n=119

Teenagers and young adults

Only 27/43 hospitals to which TYA patients were admitted had separate facilities or protocols for this group (Table 2.9). Importantly, in only 33/77 hospitals was there a policy for the transition of care from paediatrics to adult services (Table 2.10). Where there was a policy in place, the transition age varied, although was most commonly 16 years of age (Table 2.11).

Table 2.9 Hospitals to which TYA patients were admitted for SACT alongside adults had separate facilities or policies for them within the unit

	Number of hospitals
Yes	27
No	16
Subtotal	**43**
Not applicable	71
Not answered	16
Total	**130**

Table 2.10 Hospital policy for transition of care from paediatric to adult oncology services

	Number of hospitals
Yes	33
No	44
Subtotal	**77**
Not applicable (reasons given why)	40
Not answered	13
Total	**130**

Table 2.11 Transition age according to policy

	Number of hospitals
≤ 14 years	1
>14-<16 years	2
>16-18 years	25
No fixed age	3
Subtotal	**31**
Not answered	2
Total	**33**

Patient contact

Should patients wish to speak to somebody in order to seek advice, a number was provided in 113/117 (96.6%) hospitals. However, in 25/113 (22.1%) hospitals advice over the telephone was given by general rather than specialist staff. Patients were able to speak to a member of the oncology team in 92/113 (81.5%) hospitals (Table 2.12). In 97/110 (88.2%) hospitals a record of each telephone conversation was made. When patients sought advice over the telephone a record of this conversation was only made into the patient notes 41/97 of the time (Table 2.13).

The Children's Cancer Liaison Group (CCLG) has developed a 'telephone triage toolkit' which defines a framework for the provision and documentation of telephone advice, and they recommend that staff are trained in the use of this tool.[16]

Table 2.12 Who the patients would speak to

	Number of hospitals	%
Specialist oncology nurse	76	67.3
General medical/paediatric doctor	25	22.1
Haemato-oncology doctor	16	14.2
Other	44	38.9

Answers may be multiple; n=113

Table 2.13 Where the record was made

	Number of hospitals
On the handover sheet	21
Directly into the patient's notes	41
Elsewhere	58

Answers may be multiple; n=97

Should a patient be admitted with a complication of SACT to the same hospital where they had been treated, 93/112 (83%) hospitals had a mechanism for informing a named haemato-oncologist and 61/93 aimed for this information to be passed on within 24 hours of admission. Should the patient be admitted to a different hospital the mechanism to notify a named haemato-oncologist fell to 51/85 (60%).

Multidisciplinary team meetings

Patients were discussed at age appropriate multidisciplinary team (MDT) meetings in 105/109 (96.3%) hospitals.

Table 2.14 Treatment of a new patient is discussed at an age appropriate MDT meeting is mandatory

	Number of hospitals	%
Yes	105	96.3
No	4	3.7
Subtotal	**109**	
Not answered	21	
Total	**130**	

Standard operating procedures

Standard operating policies (SOPs) promote quality and safety in healthcare. The SOPs in place in hospitals responding to the questionnaire are listed in Table 2.15.

Table 2.15 The standard operating procedures/ policies in place

	Number of hospitals	%
Clinical management of neutropaenic sepsis	122	93.1
Prescription of growth factors	86	65.6
Other procedures/policies relating to SACT	87	66.4
Policy for SACT extravasation	121	92.4
Policy for SACT anaphylaxis	113	86.3

Answers may be multiple; n=131

Audit

Table 2.16 overleaf shows the areas where audit following SACT was undertaken. In 56/105 (53.3%) hospitals SACT toxicity was not audited, 82/109 (75.2%) did not audit nausea and vomiting, 60/106 (56.6%) did not audit death within 60 days of SACT, 41/106 (38.7%) did not audit central line complications and 39/102 (38.2%) did not audit the appropriateness of the last administration of SACT before death. However, audit rates were better for neutropaenic sepsis and deaths within 30 days.

Table 2.16 Audits undertaken within hospitals

	Yes	%	No	%	Subtotal	Not answered/ Unknown	Total
SACT toxicity	49	46.7	56	53.3	**105**	26	**131**
Neutropaenic sepsis	113	94.2	7	5.8	**120**	11	**131**
Nausea/ vomiting	27	24.8	82	75.2	**109**	22	**131**
Number of deaths within 30 days of SACT	96	83.5	19	16.5	**115**	16	**131**
Number of deaths within 60 days of SACT	46	43.4	60	56.6	**106**	25	**131**
Appropriateness of last dose of SACT in patients who died	63	61.8	39	38.2	**102**	29	**131**
Other topics relating to SACT	24	39.3	37	60.7	**61**	70	**131**
Central line complications	65	61.3	41	38.7	**106**	25	**131**

When deaths were discussed in Morbidity and Mortality (M&M) meetings, discussions and/or learning points were recorded in the patient notes in 39/130 (30%) hospitals. However, those not recorded in the notes were recorded in minutes of the meetings. The Royal College of Radiologists have produced a process and proforma for reviewing deaths with 30 days of SACT.[17] Organisations recorded that M&M meetings were routinely attended by the specialties listed in Table 2.17.

Most hospitals (96.1%; 99/103) participated in peer review or self-assessment exercises relating to UK cancer standards.

Table 2.17 Attendees at the oncology morbidity and mortality meeting

	Number of hospitals	%
Nurse specialists	79	75.2
Age-related oncologists	69	65.7
Age-related haemato-oncologists	69	65.7
Key workers	50	47.6
Other	36	34.3
Palliative care	30	28.6
Surgeons	11	10.5
Intensivists	9	8.6

Answers may be multiple; n=105

2

Key Findings

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 audited 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.

SEE RECOMMENDATIONS 1-2-8-9-10-14-15-16

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3

Study population

It is important to note that this study reviewed the care of patients who died or had an unplanned admission to critical care within 60 days of having received systemic anti-cancer therapy (SACT); by definition this was a high risk population.

The age distribution was as expected from the incidence of cancer in the 0-25 year old population, as was the slightly higher number of males. However, those diagnoses that required more intensive SACT and/or had a poorer prognosis were over-represented in this sample. For example, acute lymphoblastic leukaemia represented around 80% of leukaemias in this age group[18] but only 35/59 patients with leukaemia were diagnosed with this condition in this study.

Similarly, renal tumours and adrenal neuroblastoma have an equal incidence at diagnosis but in this sample there were nine cases of neuroblastoma and four of renal tumours (Figure 3.2 overleaf).

Previous work has shown that over 80% of all children with cancer are cured of their disease,[19] but in this study population over half had relapsed (69/130; 53.1%). This resulted in over 65.6% (105/160) of patients having already received at least one previous protocol of therapy with some patients having had more than six previous protocols, as shown in Figure 3.3 overleaf. This was clearly a population with high-risk disease who were already heavily pre-treated.

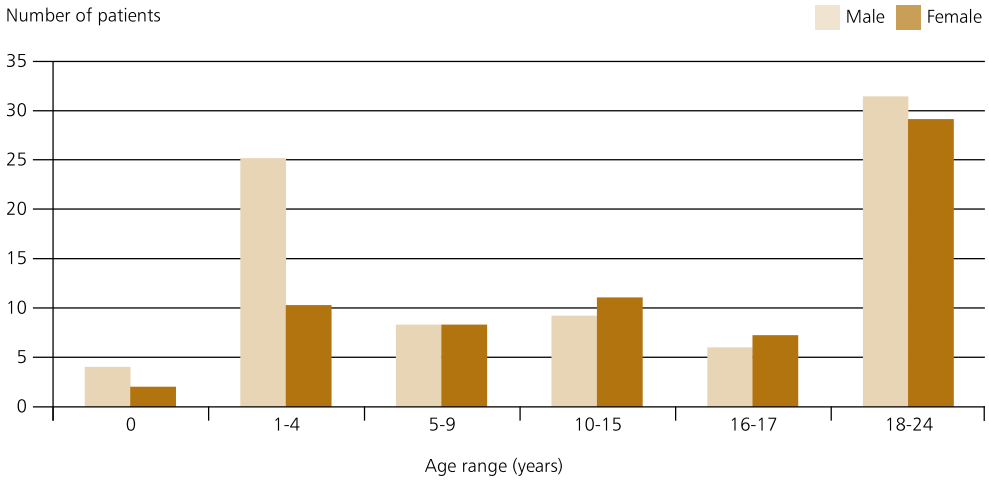

Figure 3.1 Age and gender

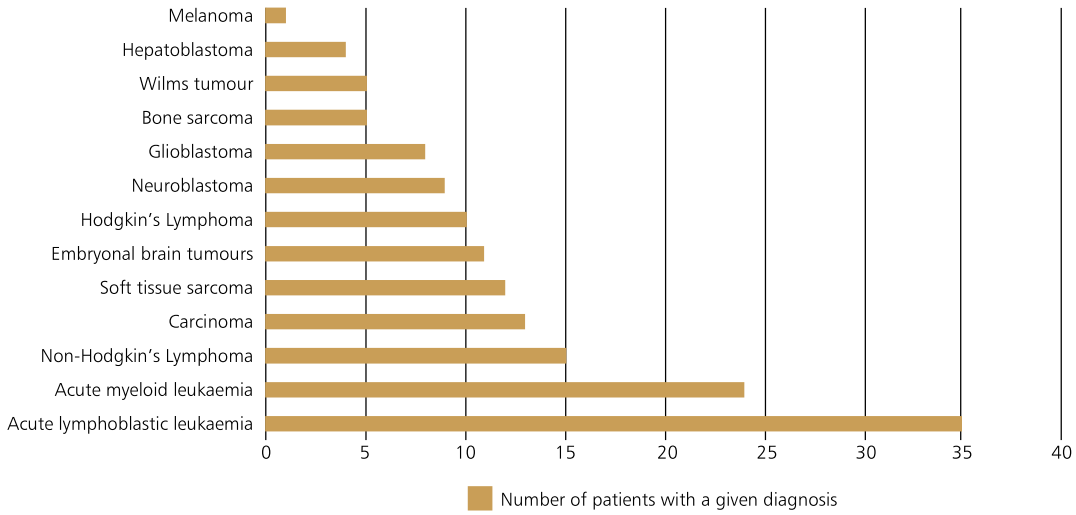

Figure 3.2 Number of patients with a given diagnosis

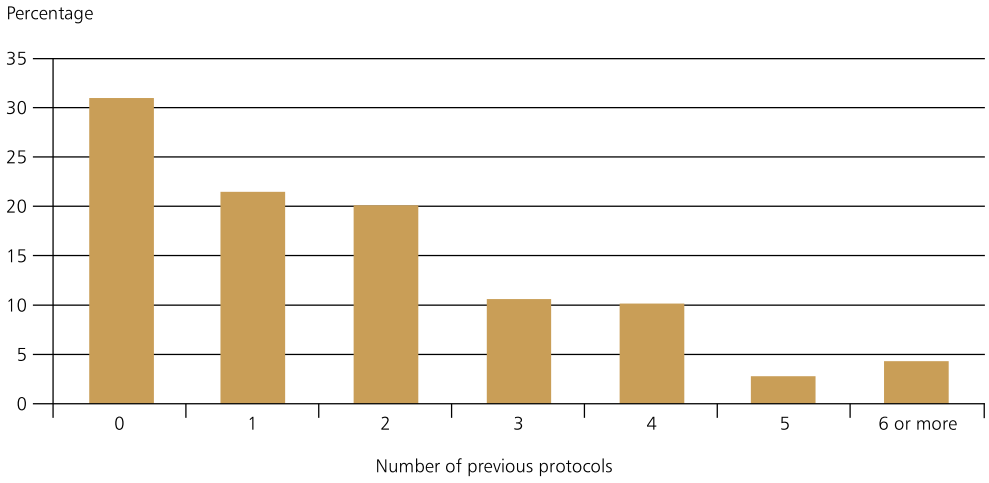

Figure 3.3 Number of previous protocols - reviewers' opinion

The presence of recurrent disease and the effects of previous therapy resulted in this population having an increased burden of comorbidities as shown in Figure 3.4.

The unplanned admission or death happened relatively early after the initiation of the most current protocol of care as shown in Figure 3.5. In 69/76 patients the event happened within three-months of the most recent SACT and in 40/76 the event happened within 30 days of initiation from the protocol, which probably represented the first cycle of this therapy.

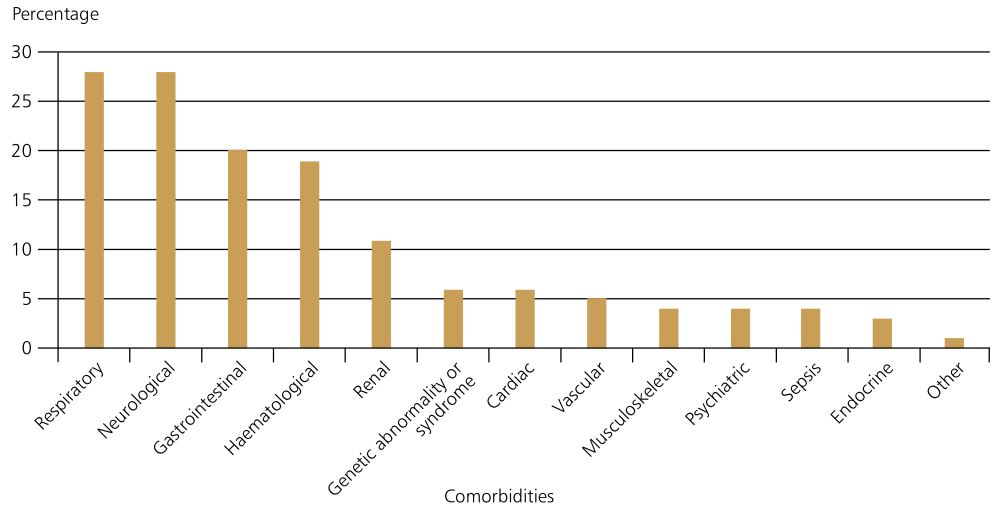

Figure 3.4 Co-morbidities at time of protocol prescription

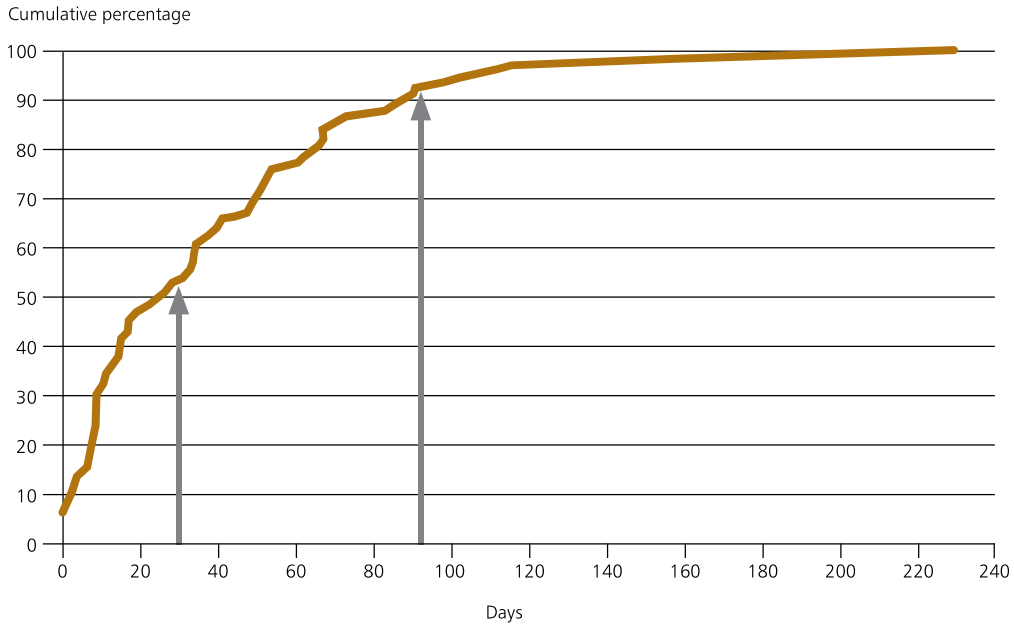

Figure 3.5 Days from start of protocol to final admission

The outcome for the population in this study was poor, only 25/135 (18.5%) patients survived three-months from the event and 93/135 (68.9%) died during the admission.

Table 3.3 Outcome of patients

	Number of patients	%
Patient died during the hospital admission	93	68.9
Patient survived	25	18.5
Patient died following discharge	17	12.6
Subtotal	**135**	
Not answered	15	
Total	**150**	

Table 3.4. shows that the majority of patients died in hospital. Although some patients and families may choose hospital as a place of death, 38/112 (33.9%) patients died in a critical care unit, suggesting that the death was either unexpected or that ceilings of treatment had not been defined before the terminal event had taken place.

Table 3.4 Place of death – reviewers' assessment form

	Number of patients	%
High dependency ward	38	33.9
Specialist adult cancer ward	21	18.8
Specialist paediatric cancer ward	17	15.2
Home	13	11.6
General paediatric ward	6	5.4
Hospice	7	6.3
General adult ward	4	3.6
Other	6	5.4
Subtotal	**112**	
Not answered	38	
Total	**150**	

Key Findings

19 The patient population in this study was high-risk with diagnoses that needed planned aggressive therapy and therefore had lower 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

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.

4

Management of systemic anti-cancer therapy

This section reviews how the decision to start the final protocol of systemic anti-cancer therapy (SACT) was made, how it was communicated to the patient and their family and how consent for therapy was obtained. Data on the assessment of the patient before the start of the protocol and how the SACT was prescribed was also explored.

Data on the fitness of the patient to receive SACT before the cycle of SACT that preceded the admission to critical care or death was analysed as part of a review of the prescribing pathway. Finally, the toxicity that resulted from the final cycle of SACT was assessed.

Table 4.1 Service overseeing prescription of SACT – clinician's opinion

	Age				
	0-11	**12-16**	**17-18**	**19-24**	**Total**
Paediatric SACT service	56	23	8	0	**87**
Adult haematology	0	0	4	27	**31**
Adult solid tumour	0	1	5	18	**24**
Other	4	3	3	8	**18**
Total	**60**	**27**	**20**	**53**	**160**

Start of final protocol of SACT

The decision to start a new protocol of therapy is a critical step in the treatment of patients with malignancy. In 111/147 (75.5%) patients the decision was made in a principal treatment centre.

The provision for children and adults was clear with each group being treated by age appropriate teams, but for teenagers the situation was more fragmented. The prescription was not undertaken in a principal treatment centre (PTC) or teenager and young adult (TYA) approved centre in 3/160 patients, all of whom were teenagers.

The protocol was initiated by a consultant in 133/159 (83.6%) patients and in no case was the protocol started by a doctor with less than ST3 level of experience. The specialty of the doctor prescribing the final cycle of SACT was appropriate in all cases reviewed, for which data were available.

The intent of the protocol is noted in Figure 4.1 which compared the intent as documented by the clinician looking after the patient with the evidence the reviewer could find in the case notes. In 16/145 (11.0%) sets of case notes the reviewers did not find evidence that the intent of treating the patient was clear.

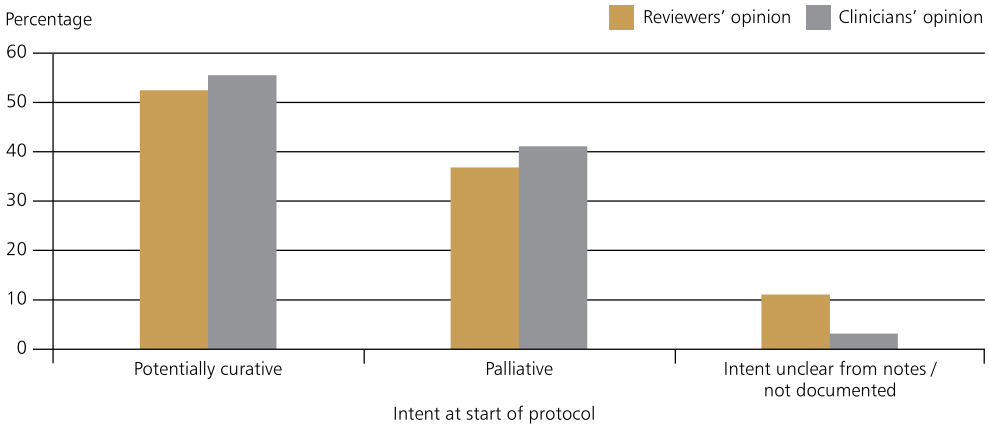

Figure 4.1 Intent at start of protocol

In 58/147 (39.5%) patients the clinician looking after the patient thought the chance of cure was less than 5% and in 5.9% (5/85) of patients treated with curative intent the clinician instigating the therapy gave the chance of cure as less than 5%.

Table 4.2 Intent of treatment recorded in the notes – clinician's opinion

	Number of patients	%
Yes	128	85.9
No	21	14.1
Subtotal	**149**	
Not answered	15	
Total	**164**	

Table 4.3 Estimated chance of cure in patient at time protocol was first prescribed – clinician's opinion

	Number of patients	%
>50%	38	25.9
>20 - 50%	30	20.4
>5 - 20%	21	14.3
<5%	58	39.5
Subtotal	**147**	
Not answered	17	
Total	**164**	

In 102/107 (95%) cases reviewed, the reviewers thought that the essential pre-SACT investigations had been carried out before the SACT was instigated for all patients. In patients treated with curative intent the reviewers thought that the timing of the start of the protocol were appropriate in 68/73 patients and the doses used were appropriate in 61/66 patients. However, these figures dropped to 41/51 and 37/48, respectively in patients treated with palliative intent. In six patients the reviewers did not feel that any SACT was appropriate as the patients were in poor clinical condition and had no realistic chance of cure.

It has been suggested that being treated on a clinical trial may improve outcome and paediatric oncology has been at the forefront of offering patients therapy on national or international clinical trials.[20] It was therefore of note that 132/161 (82%) of patients were not on a clinical trial, although 53.1% (69/130) of patients included had relapsed disease. Only five patients were on early phase clinical trials (Table 4.6).

It is possible that the relatively small number of patients on early phase clinical trials was related to the strict entry criteria these trials have with regard to both prognosis and performance status, resulting in fewer of these patients dying or having unplanned admissions to critical care within 60 days of receiving a trial medication. Better access to clinical trials for patients with resistant or recurrent disease is needed.

Table 4.4 Protocol of SACT was part of a clinical trial – clinician's opinion

	Number of patients	%
Yes	29	18.0
No	132	82.0
Subtotal	**161**	
Not answered	3	
Total	**164**	

Table 4.5 Type of trial

	Number of patients
A single-centre trial	1
A multi-centre trial	8
An industry sponsored trial	4
A national cancer research network approved trial	15
Subtotal	**28**
Not answered	1
Total	**29**

Table 4.6 Phase of clinical trial

	Number of patients
Phase 1	3
Phase 2	2
Phase 3	23
Subtotal	**28**
Not answered	1
Total	**29**

Two-thirds of patients (105/160; 65.6%) had received previous protocols of SACT. Of these 105 patients, 62 were started on the current protocol as they were not responding to previous therapy and 49 of these were also deteriorating clinically. As mentioned previously, the study population had a substantial incidence of serious comorbidity as depicted in Figure 4.2 which shows the percentage of patients with a medical complication who had a comorbidity. Patients often had more than one comorbidity so the total of the percentages add up to more than 100%.

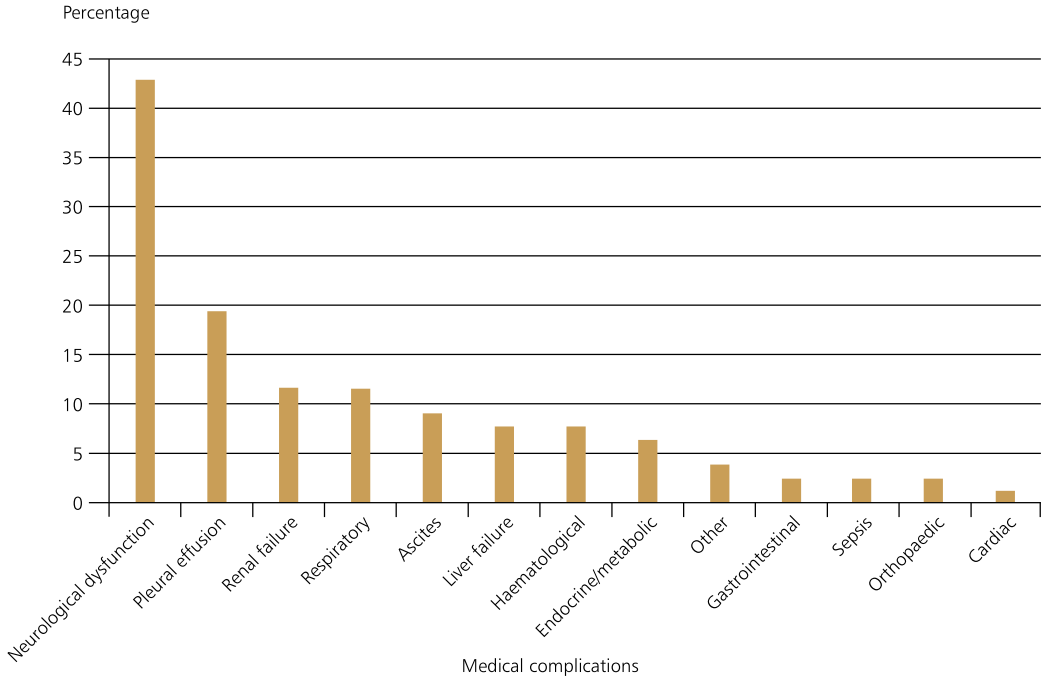

Figure 4.2 Percentage of patients with medical complications who had a co-morbidity

Table 4.7 Performance score taken immediately prior to initiation of most recent protocol of SACT – clinician's opinion

	Number of patients	%
Yes	89	54.9
No	73	45.1
Subtotal	**162**	
Not answered	2	
Total	**164**	

Despite this high comorbidity, a formal assessment of performance status before considering the protocol was not carried out in 89/162 (54.9%) patients. The exception to this was in patients treated on phase 1 and 2 clinical trials, all of whom had formal assessment of performance status performed. Early phase clinical trials routinely stipulate a minimum performance status for entry in order to prevent patients receiving SACT from which they have no realistic chance of benefit. Consideration should be given to introducing a minimum performance status for palliative SACT in all patients either on- or off-trial.

Table 4.8 Performance score used – clinician's opinion

Performance score used	Number of patients	%
Lansky	29	35.4
Karnofsky	13	15.9
Other	40	48.8
Subtotal	**82**	
Not answered	7	
Total	**89**	

As the decision to start a protocol of SACT is such a major one, the expectation is that it would be discussed in a multidisciplinary team meeting (MDT). However, the reviewers could not find any evidence of MDT discussion in 50/148 (33.8%) cases reviewed. The age group of the patient did not make a difference to the proportion being discussed, but the intent of therapy did make a difference as shown in Table 4.9.

In many ways, discussions about whether to treat someone on palliative SACT are more difficult than those for first line therapy and yet 10% fewer palliative patients were discussed in an MDT compared to patients whose treatment intent was cure.

Table 4.9 Intent at start of protocol and whether treatment was discussed at an MDT meeting – reviewers' opinion

Intent	Evidence that treatment was discussed at MDT meeting				
	Yes	No	Subtotal	Not answered	Total
Palliation	33	20	**53**	0	**53**
Cure	55	22	**77**	1	**78**
Subtotal	**88**	**42**	**130**	**1**	**131**
Not answered	10	8	**18**	1	**19**
Total	**98**	**50**	**148**	**2**	**150**

Communication and consent

Once a treatment plan has been agreed in an MDT then that recommendation needs to be discussed with the patient and their family. It is essential that the intent of therapy and the potential benefits and toxicities of therapy are discussed with the patient or their legal guardian, so that appropriate decisions can be made. The signing of the consent form is the culmination of this process.

The treating clinicians felt that the vast majority of parents and patients did understand the potential toxicity of treatment and its intent.

Table 4.10 Potential side effects were fully understood by patient/ parents – clinician's opinion

	Patient >12 years	%	Parent(s)	%
Yes	82	96.5	147	99.3
No	3	3.5	1	0.7
Subtotal	**85**		**148**	
Not applicable (patient under 12 years of age)	68		11	
Not answered	11		5	
Total	**164**		**164**	

Table 4.11 Chance of cure fully understood by patient/ parents – clinician's opinion

	Patient >12 years	%	Parent(s)	%
Yes	79	86.8	143	99.3
No	12	13.2	1	0.7
Subtotal	**91**		**144**	
Not applicable (patient under 12 years of age)	44		1	
Not answered	29		19	
Total	**164**		**164**	

Table 4.12 Benefits and risks of treatment were appropriately stated – reviewers' opinion

	Benefits		Risks	
	Number of patients	%	Number of patients	%
Yes	108	82.4	106	79.7
No	23	17.6	27	20.3
Subtotal	**131**		**133**	
Not answered	19		17	
Total	**150**		**150**	

However, in the opinion of the reviewers, 23/131 (17.6%) cases reviewed did not have the benefits appropriately documented nor the risks in 27/133 (20.3%). In the majority, the chances of cure had been overstated and the risks of toxicity understated.

The reviewers found evidence of factors that made the discussions potentially suboptimal in 14/145 (9.7%) patients. Language difficulties or learning difficulties were stated as the major causes of problems with information sharing. Only 12/162 (7.4 %) patients had recently transitioned between services (either paediatric to adolescent or adolescent to adult) and in none of these were problems with transition identified.

The reviewers found evidence that written information about chances of cure and toxicities of SACT had been provided to the patients and parents in the majority of cases, but 16/125 (12.8%) parents and 48/122 (39.3%) patients did not receive written information about toxicity or of chances of cure.

One Reviewer noted *"The patient needed more guidance at the start of therapy about the risks of the treatment not working or causing life threatening toxicities. The options of palliative SACT or symptom control alone were not discussed."*

Table 4.13 Written information was provided to patient/parents regarding chance of success and potential side effects – clinician's opinion

	Patient	%	Parent(s)	%
Yes	74	60.7	109	87.2
No	48	39.3	16	12.8
Subtotal	**122**		**125**	
Not answered	42		39	
Total	**164**		**164**	

The management of patients is shared by the principal treatment centre (PTC) with the patient's GP and secondary care hospital, yet in over half the cases the reviewers did not find evidence of any written communication about toxicity from the PTC to the GP or paediatric oncology shared care unit (POSCU) (Table 4.14). It is clear that adequate communication with the broader healthcare team is essential if the patient and their families are to be supported. Clinical trials have standard information sheets for GPs, and for non-trial treatments similar information sheets should be developed nationally to ensure consistent advice is given.

Table 4.14 Evidence that SACT treatment and potential toxicity communicated to GP/ POSCU – reviewers' opinion

	GP		Shared care centre		Other	
	n	%	n	%	n	%
Yes	52	57.1	31	43.7	11	55.0
No	39	42.9	40	56.3	9	45.0
Subtotal	**91**		**71**		**20**	
Not answered	59		79		130	
Total	**150**		**150**		**150**	

Key workers provide an invaluable link between different services involved in the complex therapy that patients require. The clinicians reported evidence of good practice with 95.5% of patients having a named key worker.

Discussions about the intent and outcomes in patients treated with palliative intent are always difficult. Whilst it might be understandable that ceilings of treatment and end of life care are not discussed at the start of the protocol in patients treated with curative intent, these discussions are integral to the package of care in patients where palliation is the aim. However, where there was adequate data to review, these discussions occurred in less than half (17/42) of the patients being treated with palliative intent. It may not be appropriate to discuss ceilings of treatment in patients being treated with curative intent, which could explain the finding that these discussions only happened in 7/58 patients.

It could be that the palliative care notes were not included in the medical notes available to the reviewers, but it would be usual to record these discussions in the medical notes or mention them in letters if they had taken place.

The consent to SACT is the culmination of the communication and discussion between the patient, their families and the medical staff. According to the consultants responsible for a patients care, consent was taken by the consultant in 83.7% (128/153) of cases and by doctors who were ST3 or above in all cases. In 96.8% (153/158) of cases there was documentation of consent in the notes. However, the reviewers only found a consent form or a copy of it, in the notes in 62.2% (92/148) of cases reviewed. Good practice dictates that as the consent form must be checked before SACT is administered, the consent form should have formed part of the medical notes. There was no difference between patients treated with curative or palliative intent as shown in Table 4.17. It is essential that a consent form or a copy is in the medical notes for the checking of SACT.

Table 4.15 Intent at start of protocol and documented discussions regarding ceilings of treatment – reviewers' opinion

Intent	Documented discussions regarding ceilings of treatment				
	Yes	No	Subtotal	Not answered	Total
Curative	7	51	**58**	20	**78**
Palliative	17	25	**42**	11	**53**
Subtotal	**24**	**76**	**100**	**31**	**131**
Not answered	0	10	**10**	9	**19**
Total	**24**	**86**	**110**	**40**	**150**

Table 4.16 Intent at start of protocol and documented discussions regarding end of life care – reviewers' opinion

Intent	Documented discussions regarding end of life care				
	Yes	No	Subtotal	Not answered	Total
Curative	3	60	**63**	15	**78**
Palliative	18	28	**46**	7	**53**
Subtotal	**21**	**88**	**109**	**22**	**131**
Not answered	2	10	**12**	7	**19**
Total	**23**	**98**	**121**	**29**	**150**

Table 4.17 Intent at start of protocol and signed consent form in the notes – reviewers' opinion

Intent	Signed consent form				
	Yes	No	Subtotal	Not answered	Total
Curative	49	28	**77**	1	**78**
Palliative	32	21	**53**	0	**53**
Subtotal	**81**	**49**	**130**	**1**	**131**
Not answered	11	7	**18**	1	**19**
Total	**92**	**56**	**148**	**2**	**150**

In those consent forms that were available, the reviewers found that the most frequent toxicities were noted in 81/85, but in only 37/85 was there documentation that SACT could be life threatening. There was no apparent difference between patients treated with curative or palliative intent. Although rare, death from SACT is a known complication and the consent forms should explicitly state this.

In terms of who gave consent, 49% (73/150) of the patients whose care was reviewed were not eligible to do so and in these cases the parents gave consent.

Children who are not legally eligible to consent to therapy should be asked for their assent. Table 4.18 shows the numbers who did assent to therapy, assessed by age group.

Table 4.18 Assent to therapy by age group

Age	Patient gave assent					
	Yes	No	Subtotal	NA	Not answered	Total
0-3 years	0	0	**0**	27	6	**33**
>3-6 years	3	1	**4**	8	4	**16**
>6-12 years	3	6	**9**	2	2	**13**
>12-16 years	7	4	**11**	3	1	**15**
Total	**13**	**11**	**24**	**40**	**13**	**77**

In 11 patients aged 12-16 years on which there were data, only seven patients gave assent to therapy. Whilst it may be that a higher proportion gave verbal assent there was no record of this in the medical notes. More attention should be paid to seeking the child's assent in this age group. The reviewers thought that the consent form was completed without errors in 75/85 of the forms that they had access to review, but commented that the generic consent forms used by most hospitals for SACT consent were not structured in such a way as to make discussions of risks and benefits of

SACT very clear. The ideal form must include the intent of therapy; either cure (with estimate of % chance of cure) or palliation. Key toxicities, including the risk of toxic death, should also be mandatory.

In 19/155 (12.3%) cases clinicians reported to feel under pressure from the families to prescribe SACT, even when the risks and benefits of therapy had been discussed in an MDT and the recommendations had then been discussed with families. Parental desire to pursue treatment directed against the tumour, even in the face of progressive disease, has been well documented[6] and represents a key challenge in the planning of care for this vulnerable population.

Table 4.19 Clinician felt under pressure to prescribe SACT at time of protocol prescription

	Number of patients	%
Yes	19	12.3
No	136	87.7
Subtotal	**155**	
Not answered	9	
Total	**164**	

A clinician stated *"The team clearly knew that the patient would not tolerate the SACT and tried to communicate this to the parents but ended up respecting the parents' wish for SACT to be given."*

Cycle of SACT

In 78/131 (59.5%) cases reviewed the unplanned admission to critical care or death occurred after the first cycle of SACT on the protocol prescribed. The grade and the specialty of doctor prescribing the SACT was appropriate in 111/112 (99.1%) of cases and it was the opinion of the reviewers that the location of SACT prescription was appropriate in 131/134 (97.8%) cases.

The SACT included a component of parenteral SACT in almost 95/108 (88.0%) cases as shown in Table 4.20.

Table 4.20 Format of SACT prescription – reviewers' opinion

	Number of patients	%
Parenteral SACT	77	71.3
Oral SACT	13	12.0
Both parenteral and oral SACT	18	16.7
Subtotal	**108**	
Not answered	42	
Total	**150**	

Oral SACT was more likely to be prescribed on a handwritten prescription than parenteral SACT as shown in Table 4.21. Electronic prescription of SACT has been mandatory in England since 2016.

Table 4.21 Format of SACT prescription – reviewers' opinion

	Parenteral	Oral
Handwritten	9	9
Pre-printed prescribing	22	4
Electronic prescribing	27	2
Subtotal	**58**	**15**
Not answered	37	16
Total	**95**	**31**

In 13/87 cases reviewed the reviewers did not find evidence that the SACT had been checked by a pharmacist.

The patients were reviewed on the day of SACT by senior staff (including consultants in almost 70% (107/154) of cases). The reason for reviewing a patient is to make sure that they are generally fit to receive the medication, to assess the toxicity of the previous cycle (to decide if any dose modifications are necessary) and to ensure that the disease is responding to therapy as expected.

As shown in Table 4.22 the vast majority of patients were assessed by senior staff on the day of SACT which was good practice.

Table 4.22 Staff grade who reviewed patient on day of SACT treatment

	Number of patients	%
Consultant	107	69.5
ST3 and above	46	29.9
Specialist nurse practitioner	22	14.3
Clinical fellow	21	13.6
Other	12	7.8
Staff grade	8	5.2
ST 1/2	5	3.2
Associate specialist	4	2.6
F1/ F2	4	2.6
Unknown	4	2.6

Answers may be multiple; n=154

Table 4.23 - Assessment of toxicity was carried out by the following – reviewers' opinion

	Number of patients	%
Consultant	49	72.1
Senior specialist trainee	8	11.8
Junior specialist trainee	0	0.0
Basic grade	2	2.9
Specialist nurse	8	11.8
Senior staff nurse	0	0.0
Staff nurse	1	1.5
Subtotal	**68**	
Not documented	11	
Total	**79**	

However, even though the assessment of toxicity had occurred and had been performed by appropriate staff in the majority of patients, there was no formal documentation in 56.0% (79/141) as shown in Table 4.24 and the use of toxicity checklists (which are readily available) was only done in a third of patients (19/64); this is despite the obligation in England to report performance status before the administration of SACT as part of the SACT dataset.[21]

Table 4.24 Evidence in notes of an assessment of toxicity since the previous cycle of SACT– reviewers' opinion

	Number of patients	%
Yes	79	56.0
No	62	44.0
Subtotal	**141**	
Not answered	9	
Total	**150**	

Table 4.25 Evidence in notes that a toxicity checklist was used – reviewers' opinion

	Number of patients	%
Yes	19	29.7
No	45	70.3
Subtotal	**64**	
Not answered	15	
Total	**79**	

There was evidence of good practice when it came to reviewing pre-treatment investigations. In 102/107 (95.3%) cases the reviewers found evidence that the pre-treatment investigations deemed as essential in the protocol had been carried out and checked. These comprised investigations such as full blood counts, electrolytes and liver function tests. However, as in the data shown from the initiation of the protocol, formal assessment of performance status was only done in half the patients (Table 4.26).

Table 4.26 Performance status assessed at the time the cycle was administered – reviewers' opinion

	Number of patients	%
Yes	61	49.6
No	62	50.4
Subtotal	**123**	
Not answered	27	
Total	**150**	

The final important check when administering SACT is that the patient is responding to the treatment as expected. With a population of relapsed patients this was particularly important as many recurrent malignancies will have developed resistance to SACT. The assessment may not necessarily be a full restaging or involve complex imaging but the treating clinician needs to exclude disease that is clearly progressing before administering a further cycle of the same therapy. A clinical assessment of response was found in 84/125 (67.2%) cases and the responses are shown in Table 4.27.

Table 4.27 Patient responding to treatment– reviewers' opinion

	Number of patients
Yes	32
No	48
Subtotal	**80**
Not answered	4
Total	**84**

One clinician reported *"The decision to treat with SACT was discussed in an MDT but the patient deteriorated before the admission, despite this the SACT proceeded anyway."*

Table 4.28 Degree of response – reviewers' opinion

	Number of patients
Complete remission	10
Partial remission	10
Minor response	6
Stable disease	2

Over a third of patients (15/41) who did not have an assessment of disease response noted were on their first cycle, where a judgment of response was not relevant. Of those patients who were not responding to therapy, the reviewers looked at whether continuing SACT was appropriate (Table 4.29).

Table 4.29 – Continuation of protocol appropriate if patient was not responding to treatment – reviewers' opinion

	Number of patients
Yes	20
No	21
Subtotal	**41**
Not answered	7
Total	**48**

Of the 41 patients for whom there were data, continuation of therapy was appropriate in 20. Although this may seem counterintuitive, many protocols have different cycles of drugs, so a patient may not respond to the first SACT cycle but may respond to the different drugs prescribed in the second.

Of the 21 patients in whom continuation of therapy was not considered appropriate, in 9 the SACT was subsequently withdrawn.

In one case the reviewers found evidence that treatment was continued, despite a lack of response, due to the wishes of the family. While one can appreciate the desire of families to continue what they see as therapy directed against the disease, the clinician has a duty to the individual patient, and continuing toxic and ineffective therapy is difficult to justify given that it will not prolong life or ameliorate pain. Discussion in an MDT would be a way of ensuring that recommendations to discontinue therapy did not rest with one clinician but were the opinion of the team as a whole. Consideration should be given to training for physicians in these conversations.

It may be understandable to continue therapy if the patient or their parents wish to, if the therapy was non-toxic and easy to administer. However, the majority of the SACT involved at least a component of parenteral therapy (Table 4.30).

Table 4.30 Method used to administer the SACT

	Number of patients	%
Oral	47	32.4
IV peripheral	13	9.0
IV through central line	108	74.5
Intrathecal	22	15.2
Subcutaneous	3	2.1
Other	5	3.4

Answers may be multiple; n=145

There was good practice in the administration of SACT with the vast majority of treatments being given by appropriately trained nurses as shown in Table 4.31.

In the opinion of the reviewers, it was appropriate to administer the final cycle of SACT in 50/55 patients. The major reasons for it not being appropriate were the poor performance status of the patient and signs of progressive disease. For 45 different patients (30%), problems were identified with the decision to give the SACT cycle (no response to treatment, performance status, investigations, timing etc. at beginning of protocol and at time of cycle).

Table 4.31 Staff who administered the most recent cycle of SACT

	Number of patients	%
Oncology nurse	92	58.6
Paediatric nurse	20	12.7
Other nurse	19	12.1
Parent/ carer	13	8.3
Oncology/ haematology consultant	8	5.1
Other	7	4.5
Paediatric oncology/ haematology consultant	6	3.8
The patient	4	2.5
Oncology/ haematology trainee	3	1.9
F1/ F2	0	0.0
Paediatric oncology/ haematology trainee	0	0.0

Answers may be multiple; n= 157

It is important that each dose of SACT that the patient has received is documented, as it allows interpretation of toxicity and efficacy. This was achieved in the vast majority of cases as shown in Table 4.32.

Table 4.32 Record of every dose of SACT that patient has received

	Number of patients	%
Yes	145	95.4
No	7	4.6
Subtotal	**152**	
Not answered	12	
Total	**164**	

However, in 43/141 (30.5%) patients the records of SACT were hardcopy and not accessible electronically. Electronic patient records have the functionality to show each dose of SACT that has been administered to a patient.

Table 4.33 Arrangement of recording every dose of SACT patient has received

	Number of patients	%
Hardcopy case notes at the hospital	43	30.5
Electronic records (accessible by secondary specialist care only)	60	42.6
Hardcopy case notes at the hospital and electronic records (accessible by secondary specialist care only)	35	24.8
Hardcopy case notes at the hospital and electronic records (accessible by secondary/primary/ community care)	3	2.1
Subtotal	**141**	
Not answered	4	
Total	**145**	

Safety netting

When a cycle of SACT is administered it is essential that the patient and the family are informed of how to recognise expected complications and what to do if they occur. The prompt recognition and treatment of neutropaenic sepsis is essential if morbidity and mortality are to be prevented; it remains the most important cause of preventable death due to therapy.

Guidance on the management of febrile neutropenia in children and adults was produced by NICE in 2012.[22] A recent audit of compliance in children has been conducted by the Children's Cancer and Leukaemia Group (CCLG). This showed that only 64% of parents or carers were given written information about febrile neutropaenia.[23]

When clinicians treating the patients in this report were asked if patients and their families had been given written information about febrile neutropenia, they responded that 94.9% (111/117) of parents and 67% (77/115) of patients answered that they had. The reviewers were only able to find evidence that the patients and parents understood how to recognise neutropaenic sepsis in 61/92 cases and knew what to do if it occurred in 52/87.

Toxicity following last cycle of therapy

The final cycle of SACT was administered without any immediate complications in nearly all patients. Fever and signs of sepsis occurred in 6 of the 8 patients who did experience immediate problems.

Two-thirds (80/123; 65.0%) of patients experienced a common toxicity criteria (CTC) grade 3 or 4 toxicity following their SACT. The nature of these toxicities is shown in Figure 4.3.

Haematological toxicity was expected but the relatively high incidence of renal impairment and multi-organ failure was indicative of the poor performance status and multiple previous therapies that characterised the clinical course of some patients in this study.

There was evidence of good practice with only 2/72 patients delaying reporting of their symptoms and 70/71 clinicians assessing patients within 24 hours of the first report of symptoms.

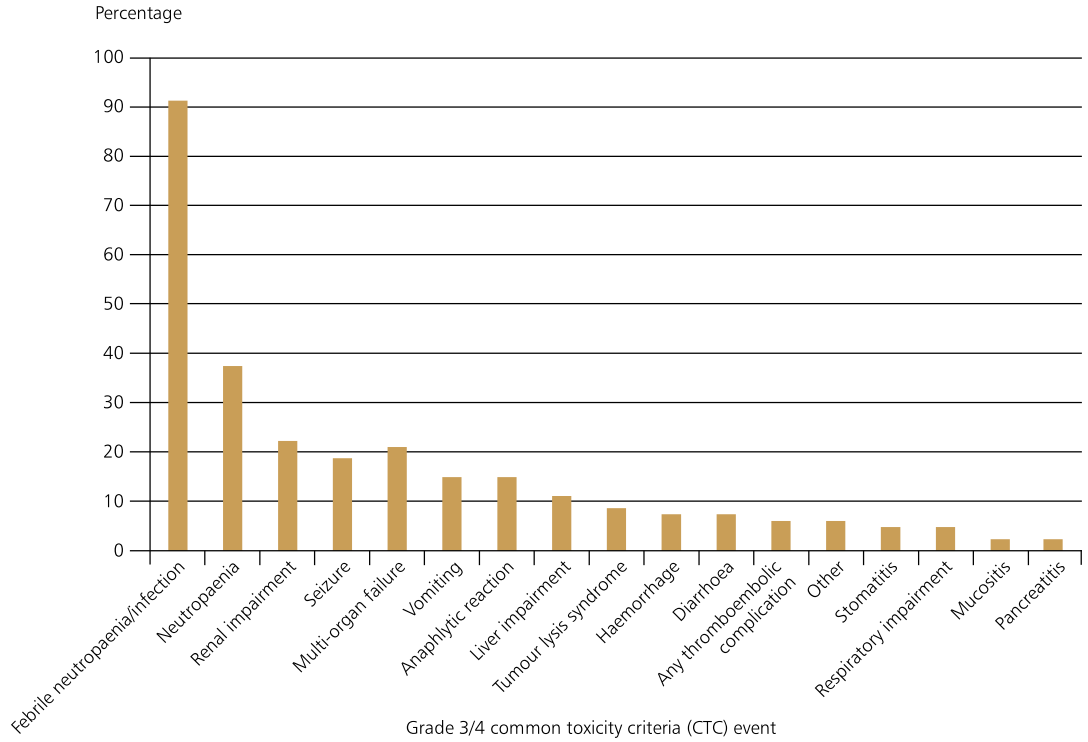

Figure 4.3 Grade 3/4 CTC event following most recent cycle of SACT

In 62.1% (64/103) of cases there was contact with medical services following the final cycle of SACT but before the final admission to hospital. The majority of these assessments took place in hospital (Table 4.34).

Some patients had multiple contacts with the medical services before their last admission, in 11 patients there were 4 or more contacts.

Reviewers stated that in 101/107 (94.4%) cases there were no missed opportunities for earlier intervention in the management of toxicity.

Table 4.34 First assessment of patient

	Number of patients	%
Patient was already an inpatient on the ward	42	60.0
Urgent specialist hospital admission	11	15.7
Routine hospital appointment	5	7.1
Urgent local hospital review same day	4	5.7
Phone conversation	2	2.9
Attendance at the emergency department	4	5.7
SACT helpline	1	1.4
Urgent local hospital admission	1	1.4
General practitioner review	0	0.0
Urgent specialist hospital appointment	0	0.0
Subtotal	**70**	
Not answered	10	
Total	**80**	

4

Key Findings

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 85.9% (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

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 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.

SEE RECOMMENDATIONS 1-2-3-4-5-6-7-8-10

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5

Final admission to hospital

The reviewers considered that 131/134 (97.8%) patients were admitted to an appropriate location within the hospital; 32/84 patients were admitted out of normal working hours.

Table 5.1 Time of admission to hospital

	Number of patients	%
00:00-07:59	7	8.3
08:00-17:59	52	61.9
18:00-23:59	25	29.8
Subtotal	**84**	
Not answered	66	
Total	**150**	

The patient's pathway of admission is shown in Table 5.2

Patients were admitted as emergencies in 69.2% (90/130) of cases and electively in 30.8% (40/130) of cases. Of the emergency admissions 18 patients came via the emergency department. The reviewers were of the opinion that there was a delay in assessment by a doctor of any grade in only seven patients hence 92.9% of patients were reviewed by a doctor in a timely manner.

Table 5.2 Route of admission to hospital

	Number of patients	%
Transfer from other hospital or hospice	29	25.4
Self-referral to ward	23	20.2
Elective/ planned admission	22	19.3
Emergency department	18	15.8
Following clinic	16	14.0
Following telephone conversation	10	8.8
GP referral	4	3.5
Already an inpatient	4	3.5

Answers may be multiple; n=114

The reviewers considered the initial assessment of patients to be generally good with minor room for improvements (Figure 5.1).

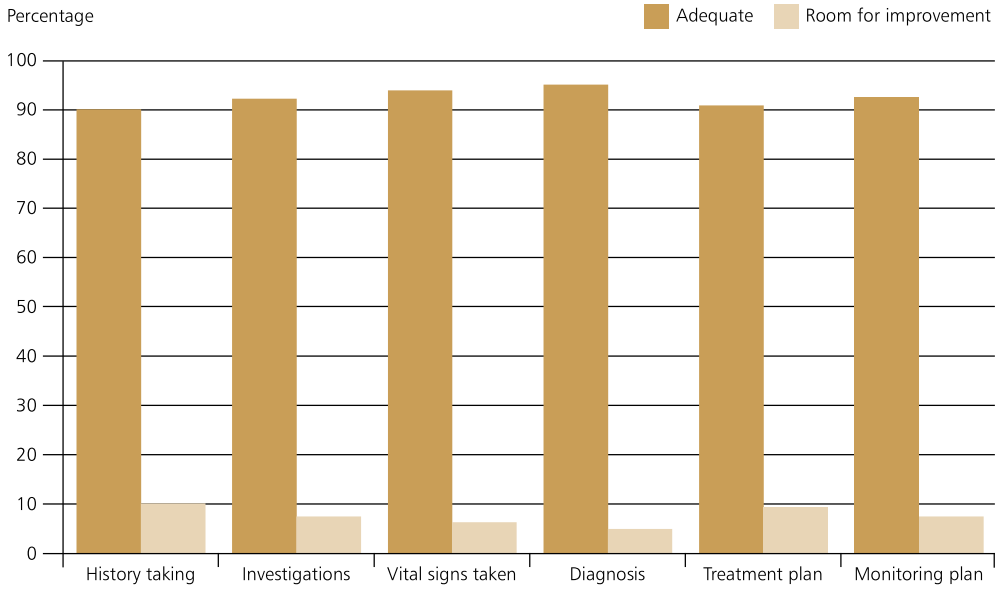

Figure 5.1 Quality of initial assessment by a doctor following admission to hospital

There were 63.8% (83/130) of patients who were admitted under haematology/oncology, paediatric oncology, oncology and teenager and young adult (TYA) cancer. Other specialties are shown in Figure 5.2.

The reviewers considered that the initial management of these patients was undertaken by the appropriate specialty in 130/131 (99.2%) of cases, without delay and appropriate investigations were undertaken. However, the Royal College of Paediatrics and Child Health (RCPCH) guidelines recommend that acute admissions should be reviewed by a consultant within 14 hours of admission.[24] One in three (12/39) of these patients were not reviewed by a consultant within that time period. The CCLG audit of febrile neutropaenia also found that a third of patients admitted with febrile neutropaenia were not seen by a consultant in the first 24 hours of admission.[23]

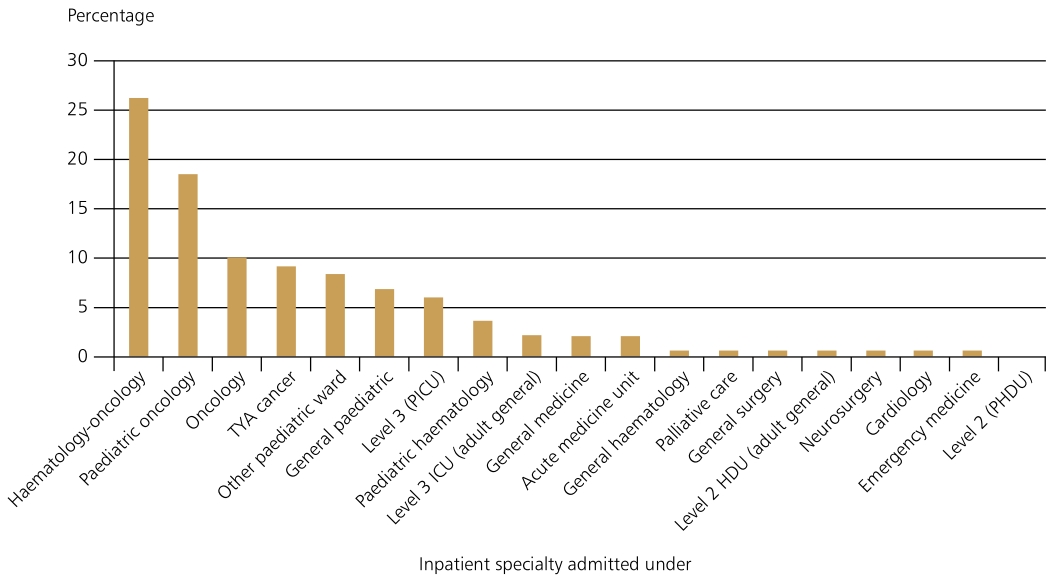

Figure 5.2 Specialties patient was first admitted under

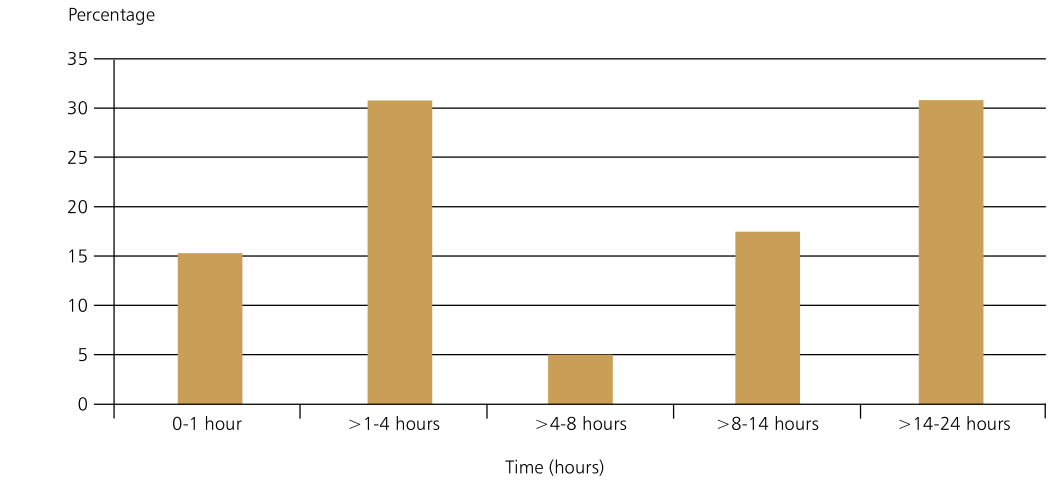

Figure 5.3 Time to consultant review

The delay in being reviewed by a consultant is of note, as 8/12 patients who were reviewed later than 14 hours after admission, were acutely unwell with significant complications relating to disease progression or SACT toxicity. None had low risk febrile neutropaenia. Furthermore, the reviewers found evidence that consultant review positively altered care, as shown in Figure 5.4.

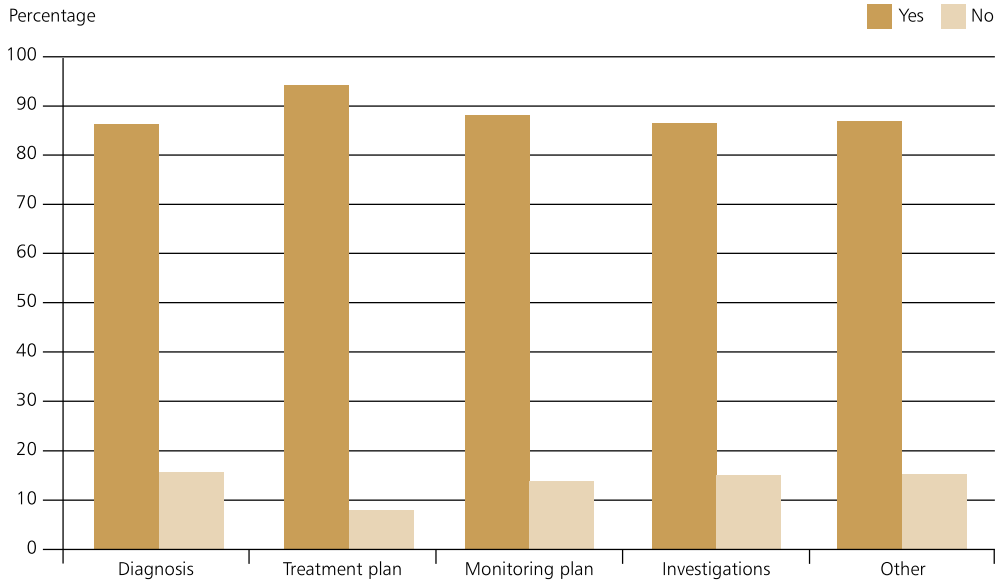

Figure 5.4 Impact of consultant review

Recognition of the sick patient remains a theme throughout NCEPOD studies. In this cohort of patients vital signs were appropriately recorded and reviewers considered this to be good practice. Two areas less well measured appeared to be blood glucose and GCS/AVPU/mental status. Children in the early stages of neutropaenic sepsis may not appear profoundly unwell and hence fewer investigations might be considered necessary. Lactate may be a more appropriate investigation in this group than blood glucose. However, measurement of lactate was performed in only 15% of patients in the recent CCLG audit of febrile neutropaenia.[23]

The use and value of early warning scores (EWS) to identify deteriorating adult patients has been highlighted in previous NCEPOD reports. In 77/88 admissions there was evidence of an EWS being used. The most common score used was The Paediatric Early Warning System (PEWS) (25/70).[25]

Table 5.3 Patient's status recorded on an early warning score on admission

	Number of patients
Yes	77
No	11
Subtotal	**88**
Not applicable	28
Not answered	18
Total	**134**

The reviewers considered that the necessary investigations were requested in 122/127 (96.1%) patients, inappropriate tests were only requested in 11/118 (9.3%) patients and there was evidence of delay in investigation in 7/123 (5.7%) patients.

Multiple specialties were involved in the care of patients from the time of admission until their death or admission to the Paediatric Intensive Care Unit (PICU). The specialties are listed in Table 5.4. This demonstrates the appropriate multidisciplinary input needed in these patients.

Table 5.4 Specialties involved in care of patient from admission to death/admission to (P)ICU

	Number of patients	%
Palliative care	47	37.6
Other	46	36.8
Paediatric oncology	40	32.0
Adult haematology	33	26.4
Teenager and young adult team	33	26.4
Pain team	25	20.0
Adult oncology	22	17.6
Paediatric haematology	22	17.6
Anaesthesia	21	16.8
General paediatrics	14	11.2
Neurosurgery	11	8.8
General surgery (paediatric)	10	8.0
General medicine (adult)	9	7.2
Adult oncology service	7	5.6
General surgery (adult)	7	5.6

Answers may be multiple; n=125

In 6/112 patients there was some disagreement in the ongoing care of the patient. These areas of disagreement included:

1. Multi-organ failure. Steroid therapy and the risk of fungal disease
2. MDT findings not shared with other specialties involved. Inappropriate outcome opinions
3. Diagnosis of malignant disease influencing critical care decision

CASE STUDY 1

A young teenager relapsed with acute myeloid leukaemia. Due to the complexity of their case, it was discussed at a national multidisciplinary team meeting to allow input from an increased number of specialists in the field. The parents' wishes were also taken into account, especially regarding how to approach the child with information about disease progression.

The reviewers considered this to be a good example of the required level of multidisciplinary involvement in difficult decisions. The reviewers considered that the patient was well looked after.

The reviewers considered that 34/133 (25.6%) patients had signs of sepsis on admission. The clinicians responsible for the patients recorded that 37/122 (30.3%) had signs of sepsis on admission. They also recorded that 31/79 patients showed signs of sepsis whilst in hospital.

CASE STUDY 2

An older teenager with relapsed Hodgkin's Lymphoma underwent allogenic stem cell transplant to consolidate the chance of cure. The patient was discharged home. A month later the patient presented with fever and infection. The patient was admitted to critical care with multi-organ failure and died there a week later.

When the patient had been seen in clinic a few days before admission there was a 3 day history of infection which had not been investigated further. English was not the family's first language.

The reviewers considered that this case exemplified the need for patients and relatives to be made aware of possible complications, how to recognise them and what to do in the event of a complication occurring.

The importance of early administration of antibiotics in patients with sepsis is established. Previous studies by NCEPOD and MBRRACE-UK have shown that there is room for improvement in the timing of antibiotic delivery.[26,27] In this current study 12/19 patients with suspected sepsis received antibiotics more than one hour following admission. Reviewers were concerned that busy hospitals and the 'cancer' label might be factors in this delay. The geographical distance to hospital may also have been a factor.

One Reviewer reported *"An 8 hour delay in starting antibiotics in a deteriorating patient with febrile neutropaenia, in which the patient had a cardiac arrest less than 2 hours after eventually starting antibiotics.'*

On admission the reviewers considered that 41/131 (31.3%) patients had other problems relating to toxicity of the SACT. The reviewers considered that only four patients received inappropriate treatment.

Patients admitted with the effects of SACT may need a higher level of care than that provided on a general ward. Of the 93/144 (64.6%) patients in this cohort 83 referred for higher care were accepted. However, in only 37/68 was there any evidence of a discussion between referrer and the intensivist regarding the appropriateness of critical care. In 14/18 cases there was evidence that the family had been involved.

Of equal importance should be the intent of the admission to critical care. In 36/56 of patients there was a documented discussion between the oncologist and intensivist regarding the intent of the critical care admission (Table 5.5).

When looking at the intent of admission in the "other" group in Table 5.6 they were appropriate reasons for critical care admission, such as to improve respiratory deterioration, intubation, post-surgical admission and to manage seizures.

Table 5.5 Documented discussion between intensivist and oncologist regarding intent of admission to (P)ICU

	Number of patients
Yes	36
No	20
Subtotal	**56**
Not applicable	8
Not answered	10
Total	**74**

Table 5.6 Intent at time of (P)ICU admission

	Number of patients
Cure	57
Palliation	3
Unknown	1
Other	12
Subtotal	**73**
Not answered	1
Total	**74**

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.

On admission to critical care reviewers found ceilings of treatment were in place in 11/60 patients. Where there were no ceilings of treatment in place, reviewers felt there should have been in 12 of these. If curative and palliative intent were separated there remained a failure to establish ceilings of care, although numbers were small in the palliative care group.

Table 5.7 Ceilings of treatment in place for critical care admission

	Curative	Palliative	Subtotal	Unclear/ not documented	Total
Yes	9	1	**10**	1	**11**
No	36	6	**42**	7	**49**
Subtotal	**45**	**7**	**52**	**8**	**60**
Not answered	15	5	**20**	3	**23**
Total	**60**	**12**	**72**	**11**	**83**

Of those patients admitted to PICU/critical care 40/71 received ventilator support, 36/69 received inotropes and 29/72 received other organ support.

Table 5.8 Patient received mechanical ventilatory support

	Number of patients
Yes	40
No	31
Subtotal	**71**
Not answered	3
Total	**74**

Table 5.9 Patient received inotropic support

	Number of patients
Yes	36
No	33
Subtotal	**69**
Not answered	5
Total	**74**

Table 5.10 Patient received support for other organ support

	Number of patients
Yes	29
No	43
Subtotal	**72**
Not answered	2
Total	**74**

CASE STUDY 3

A young adult was admitted to hospital with a diagnosis of methotrexate CNS toxicity. The known poor prognosis associated with this was recognised. A short period on critical care was given to see if any progress was made, none was seen. The patient underwent a lengthy period of ventilation. Oral SACT was given 'just in case' without consent being taken.

The reviewers were of the opinion that whilst the admission to critical care was appropriate, this situation demonstrated the need to set ceilings of treatment on, or preferably prior to, admission to critical care.

Disease progression

The reviewers were of the opinion that the patient's deterioration was due to tumour progression in 57.7% (79/137) of patients and that this was appropriately communicated to the patient's family in 68 of the patients.

Table 5.11 Evidence that treatment options relating to deterioration were discussed

	Patient	Family	Other appropriate healthcare professionals
Yes	29	69	58
No	20	3	2
Subtotal	**49**	**72**	**60**
Not applicable	24	0	0
Not answered	6	7	19
Total	**79**	**79**	**79**

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 in 69/72 cases.

The management of the end of life remains integral to the quality of patient care. Clinicians need to discuss all options with patients who are nearing the end of their life. Advanced directives, place of care, place of death and end of life pathways should be discussed as part of care planning. Figure 5.6 shows the proportion of patients in both palliative and curative streams of care in whom there was evidence that discussions took place. There is room for improvement in this aspect of care. Treatment escalation plans exist and the RESPECT form may be used in children, which would be a suitable framework on which to pin discussions around these aspects of care to ensure agreed plans are in place.

CASE STUDY 4

An infant with refractory acute lymphoblastic leukaemia had had 3 protocols of SACT. The patient had been in hospital for a lengthy period. Palliative SACT was given at a principal treatment centre in the face of a poor performance score. There was good documentation of discussions. Ceilings of treatment were established but the reviewers considered them higher than might be expected because of the parent's opinions and input.

The reviewers considered that this case was an example of parents finding it difficult to accept information about no realistic chance of cure despite daily discussions between medical/palliative care teams and the family. This case highlighted the difficulty in being able to accomplish a treatment plan that concentrates on quality of life and supportive care without the need for ongoing SACT which the family might have considered to have curative intent.

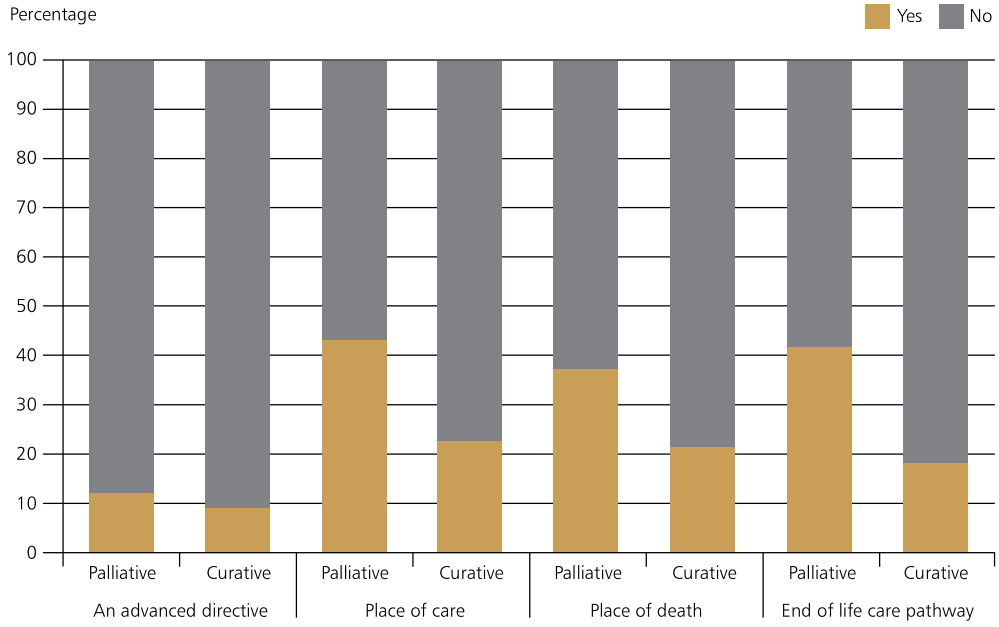

Figure 5.6 Communication of care decisions in patients for palliative and curative SACT treatment

The reviewers examined whether "no treatment with curative intent" was offered as an option and compared the curative and palliative intent groups. Five patients in the curative intent group were offered this course of treatment. When the data from these five patients were examined more closely all had already been through at least one protocol of SACT and had a very poor prognosis. The reviewers commented that even at less than 5% chance of cure, many physicians would still consider this to represent a justifiable reason to undertake SACT.

Data from the clinician questionnaire showed ceilings of treatment were discussed at some point during the admission in patients in the palliative group (63/64) and in half of patients in the curative group (44/87). For patients being treated with curative intent to have ceilings of care may seem counterintuitive but many patients being treated with curative intent in this cohort had a chance of survival of under 5%.

The reviewers were of the opinion that throughout the whole patient pathway, there were adequate discussions recorded in the case notes regarding ceilings of treatment/ end of life care decisions in 61/95 cases. The reviewers felt that these discussions would be facilitated by the co-location of the age appropriate oncology and intensive care units.

During the final hospital stay the palliative care team were recorded in the notes as being involved in 50% of patients. Of the 67 patients in whom there appeared to be no involvement, 12 were in the palliative care group.

Table 5.12 Palliative care/ceiling of treatment discussions took place at any point in the care of this patient

	Number of patients	%
Yes	112	71.8
No	44	28.2
Subtotal	**156**	
Not answered	9	
Total	**165**	

Out of the 67 patients where there was no palliative care team involvement, 65 were admitted to a hospital that submitted an organisational questionnaire stating they have a palliative care team. Fifty-eight patients had Do Not Attempt CPR (DNACPR) forms in their notes. Unfortunately, five patients in this cohort had resuscitation attempts made regardless of a DNACPR form.

Over one-third of patients were discharged alive from hospital (52/145). The reviewers considered the discharge planning to be appropriate for 30 patients.

Ninety-three patients died in hospital, of these, 61 showed deterioration relating to their tumour progression. Twelve of this group died on a high dependency unit (Figure 5.7).

The reviewers were asked to evaluate if the patient's death had in any way been related to the course of SACT. 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. This is similar to the finding in adult cancer care in the 2008 NCEPOD report.[1] A further 24.5% (26/106) had some toxicity from SACT but would have died at about the same time from disease progression or co-morbidities.

Death certificates or the cause of death as shown on a standard death certificate were present in only 36/93 of cases. In only 5/93 was there evidence of an autopsy being performed. In the 80 cases where an autopsy was not performed, the reviewers felt it should have been performed in 8. Autopsies are useful in gaining knowledge and perhaps improving therapy for those who follow but are also useful in counselling families after the death of a relative.[28] 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. The intent of morbidity and mortality meetings is audit and learning, however, the conclusions can be valuable in counselling families of bereaved patients who may only seek to discuss the death a long time after the event.

Following the death of a patient all families were offered bereavement support.

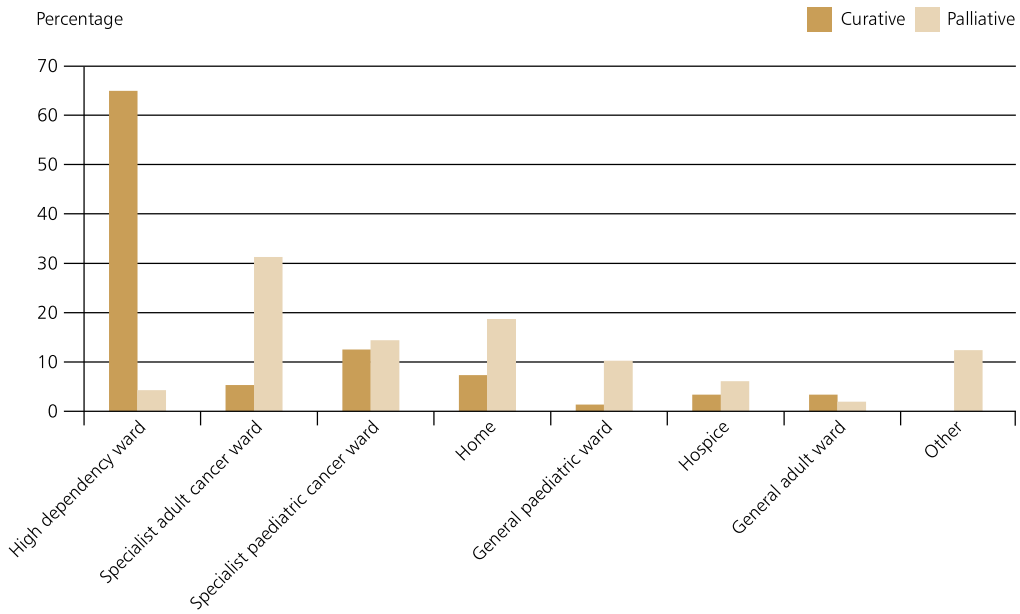

Figure 5.7 Place of death by nature of the treatment

Key Findings

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 with febrile neutropaenia 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.

SEE RECOMMENDATIONS 11-12-13-15

6

Overall quality of care

Overall quality of care

The reviewers were asked to assign a grade to the overall care received by each patient in the study.

Overall care was rated as good in 85/145 (58.6%) cases. The reviewers judged that there was room for improvement in clinical and/or organisational care in 60/145 (41.4%). There were no patients that reviewers felt the overall care received was less than satisfactory, but for 5 patients reviewers did not feel they were able to grade the quality of care due to insufficient data (Table 6.1 and Figure 6.1)

Table 6.1 Overall quality of care - Reviewers' opinion

	Number of patients	%
Good practice	85	58.6
Room for improvement clinical	40	27.6
Room for improvement organisational	15	10.3
Room for improvement (clinical and organisational)	5	3.4
Less than satisfactory	0	0
Subtotal	**145**	
Insufficient data	5	
Total	**150**	

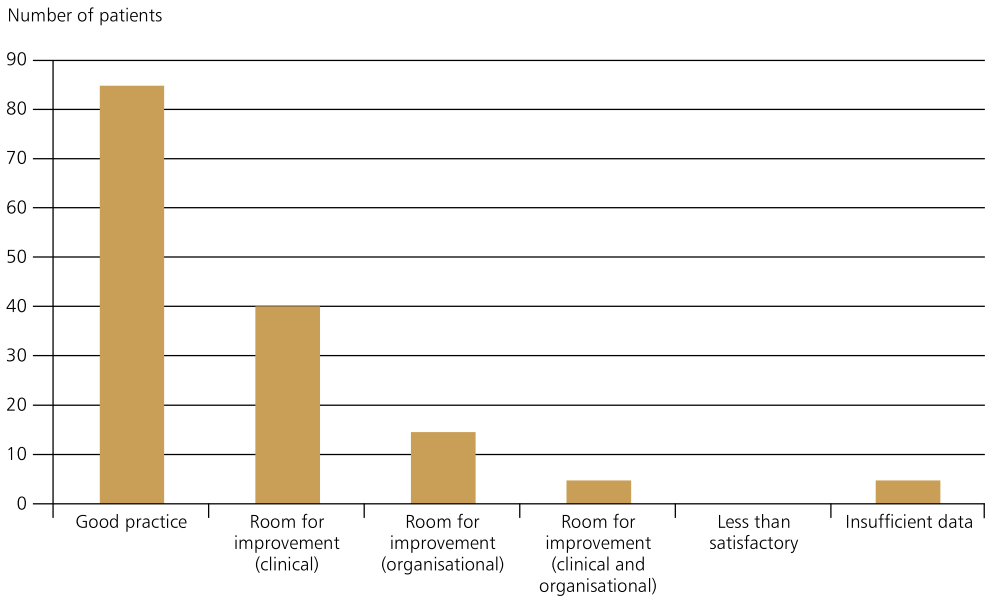

Figure 6.1 Overall quality of care - Reviewers' opinion

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Recommendations

	Recommendation	Study key findings
1	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)***	• There were no MDT discussions about starting a protocol of SACT in 33.8% (50/148) of patients • Patients were discussed at age appropriate multisciplinary team meetings in 105/109 (96.3%) hospitals
2	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. ***(Medical Director, Director of Nursing, Oncology Consultants, Specialist Nurses)*** NB: This is already linked to a CQUIN in England	• 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 49.6% (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	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)***	• 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

	Recommendation	Study key findings
4	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)***	• 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	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. ***(Consultants)***	• In 12-16 year old patients, assent was only recorded in 7/11 cases
6	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. ***(Consultants, Lead Cancer Nurse and Specialist Nurses)***	• 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	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 ***(Medical Director, Director of Nursing, Consultants, Lead Cancer Nurse and Specialist Nurses, Oncology Pharmacists)***	• 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	Assess at the point of prescribing, and again at the time of any subsequent cycles of systemic anti-cancer therapy (SACT), the following: a. Toxicity of any previous SACT cycles b. Disease response to treatment c. The patient's performance status ***(Medical Director, Director of Nursing, Consultants)***	• 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

	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)***	• 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)***	• 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)***	• 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 '*Facing the Future*' and the Royal College of Physicians of London in the *'Acute Care Toolkit 4'.* ***(Medical Director, Director of Nursing, Consultants)***	• 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)***	• 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

	Recommendation	Study key findings
14	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. ***(Medical Director, Director of Nursing, Consultants, Specialist Nurses)***	• 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	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. ***(Medical Director, Director of Nursing, Consultants, Specialist Nurses)***	• 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	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. ***(Medical Director, Director of Nursing, Oncology Consultants, Specialist Nurses)***	• In only 33/77 of hospitals was there a policy for the transition of care from the paediatric service to adult services

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Appendices

Glossary

Acute lymphoblastic leukaemia	ALL	ALL is a malignancy that starts from primitive white blood cells and is found mostly in children. There are a number of subtypes with therapy and prognosis being dependent on factors such as age, clinical presentation and subtype.
Acute myeloid leukaemia	AML	AML is a malignancy that starts from primitive myeloblast cells (the cells that would normally be important in killing bacteria and other infectious agents). AML can occur in people who have been exposed to anti-cancer treatments and those who have pre-existing blood conditions but in children it usually occurs in patients with no obvious risk factors. There are a number of subtypes with therapy and prognosis being dependent on factors such as age, clinical presentation and subtype.
Allogeneic stem cell transplant		In an allogeneic transplant, stem cells are collected from an immuno - logically matched donor and transplanted into the patient to suppress a malignancy and to restore the patient's immune system.
Assent		The expression of approval or agreement.
AVPU Scale (Alert, Voice, Pain, Unresponsive)	AVPU	A system by which a health care professional can measure and record the level of consciousness of a patient.
Bone sarcoma		A type of cancer that starts in the bone.
British Association of Cancer United Patients booklets	BACUP	Information booklets specifically written for cancer patients.
Chemotherapy anaphylaxis		Chemotherapy anaphylaxis is a severe allergic reaction to a chemotherapy drug, which can cause shock, low blood pressure, and occasionally death.
Chemotherapy extravasation		Chemotherapy extravasation refers to the inadvertent infiltration of chemotherapy into the subcutaneous or subdermal tissues surrounding the intravenous or intra-arterial administration site.
Children's Cancer and Leukaemia Group	CCLG	A children's cancer charity and professional association for those involved in the treatment and care of children with cancer.
Critical care unit	CCU	A ward for the specialised care of patients whose conditions are life-threatening and who require comprehensive care and constant monitoring.
Common Toxicity Criteria	CTC	The common toxicity criteria is used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis.

Eastern Cooperative Oncology Group	ECOG	A scale of performance status describing a patient's level of functioning in terms of their ability to take care of themselves, daily activity and physical ability.
Embryonal brain tumours		A heterogeneous group of neoplasms that primarily occur in infants and young children.
Glasgow Coma Scale	GCS	A neurological scale which aims to give a reliable and objective way of recording the conscious state of a person for initial as well as subsequent assessment.
Glioblastoma		Also known as glioblastoma multiforme (GBM), is one of the most aggressive cancers that begins within the brain.
Granulocyte colony stimulating factor	GCSF	Having chemotherapy for cancer can affect bone marrow reducing the ability to make new white blood cells. To strengthen the immune system, GCSF (a protein) may be prescribed to make more white blood cells.
Haematology		A branch of medicine concerned with the study of the cause, prognosis and treatment of diseases related to blood.
Hepatoblastoma		Hepatoblastoma is a very rare cancerous tumour that starts in the liver. This disease primarily affects children from infancy to about 3 years of age.
Hodgkins lymphoma		Cancer of the lymphatic system where the lymphoma contains Reed-Sternberg cells.
Intravenous bolus	IV bolus	A volume of fluid or dose of a drug or test substance given rapidly intravenously.
Lansky/Karnofsky Performance scores		Types of performance scores which are used to determine the function status of a patient. The Lansky score has been designed for patients aged <16 years old, the Karnofsky score is designed for patients aged ≥16 years old.
Melanoma		A type of cancer that develops from the pigment-containing cells known as melanocytes. Melanomas typically occur in the skin, but may rarely occur in the mouth, intestines, or eyes.
Neuroblastoma		A type of cancer that forms in certain types of nerve tissue. It most frequently starts from one of the adrenal glands, but can also develop in the neck, chest or abdomen.
Neutropaenic sepsis		A life threatening complication of anticancer treatment, the term is used to describe a significant inflammatory response to a presumed bacterial infection in a person with a low white blood cell (neutrophil) count with or without fever.
Non-Hodgkins lymphoma		Cancer of the lymphatic system where the lymphoma does not contain Reed-Sternberg cells.
Paediatric intensive care unit	PICU	A unit delivering Level 2/Level 3 paediatric care for critically ill infants, children and teenagers (usually up to the age of 17).

Paediatric Oncology Shared Care Units	POSCU	A paediatric oncology shared care unit (POSCU) is a hospital nearer to the child's home (for example a district general hospital). The POSCU works in partnership with the principle treatment centre (PTC), to offer the child supportive care closer to home e.g. blood transfusions, antibiotics, blood tests. Some POSCU give chemotherapy, as prescribed by the PTC, as well. The services available at POSCU in different parts of the country vary but they all offer valuable care to patients and their families closer to their homes.
Parenteral		A route of administration is the path by which a drug or fluid is taken into the body. A parenteral route is any route that is not enteral (oral).
Principal Treatment Centres	PTC	A PTC is an age appropriate centre where a patient will be diagnosed with cancer and the treatment plan decided.
Regimens		Also known as protocols. A regimen of chemotherapy defines the drugs to be used, the dosage, frequency and duration of treatments. Many regimens combine several chemotherapy drugs in combination chemotherapy.
Renal tumours		Tumours or growths on or in the kidneys.
Soft tissue sarcoma		Soft tissue sarcomas develop in supporting or connective tissue such as muscle, nerves, tendons, blood vessels and fatty and fibrous tissues. They commonly affects the legs, arms, torso, head and neck and the genitourinary system.
Specialist Children's Hospitals	SChH	A major hospital for providing services for children.
Standard Operating Procedures	SOPs	A set of step-by-step instructions complied by an organisation that are required to be initiated and followed when specific circumstances arise.
Systemic anti-cancer therapy	SACT	Encompasses both biological therapy (therapies which use the body's immune system to fight cancer or to lessen the side effects that may be caused by some cancer treatments) and cytotoxic chemotherapy (a group of medicines containing chemicals directly toxic to cells preventing their replication or growth, and so active against cancer).
Teenager and young adult	TYA	For the purpose of this study teenager and young adult includes all patients aged 16-24.
World Health Organisation	WHO	A specialised agency concerned with international public health.
Wilms tumour		A cancer of the kidneys that typically occurs in children, rarely in adults.

Appendix 1 - Shared Care Levels for POSCUs (From CHILDREN'S CANCER MEASURES GATEWAY No.12770 - APRIL 2014)

POSCU Level 1 Services

- inpatient supportive care including care of children with febrile neutropœnia
- outpatient supportive care
- outpatient follow up
- outpatient oral chemotherapy
- outpatient IV bolus chemotherapy
- exclusions - day care infusional chemotherapy, inpatient chemotherapy and all exclusions listed in Level 3.

Allowable options from the above:

1 all the above services
2 opt out of outpatient IV bolus chemotherapy only
3 opt out of outpatient IV bolus chemotherapy and inpatient supportive care including care of children with febrile neutropœnia
4 opt out of all chemotherapy and inpatient supportive care including care of children with febrile neutropœnia

NB: The implication of this is that any service that is providing outpatient IV bolus chemotherapy should also provide care of children with febrile neutropœnia.

POSCU Level 2 Services

- as for Level 1 and in addition day care infusional chemotherapy
- exclusions - inpatient chemotherapy and all exclusions listed in Level 3.

POSCU Level 3 Services

- as for Level 2 and in addition inpatient 24-hour chemotherapy
- an intrathecal chemotherapy service in a POSCU is an option for Level 3 (only) providing the following are fulfilled:
  1 compliance with HSC 2003-010, as verified by a satisfactory peer review against the ITC measures (Manual for Cancer Services 2004, section 3C-3, or any measures which supersede it);
  2 paediatric anaesthetic service
  3 agreement by CCNCG.

Level 3 Exclusions, for instance services which should only be offered in a PTC

1 final diagnosis and determination of treatment plan;
2 chemotherapy regimens or other procedures which would be rendered unacceptably hazardous or have their effectiveness reduced by reason of the limits of infrastructure or experience available at any of the POSCUs; these regimens and/or procedures should be specified at any one time for the CCN by the CCNCG;
3 stem cell transplantation;
4 recruitment to, and co-ordination of, phase I, II and III clinical trials;
5 radical radiotherapy.

Appendix 2 - The role and structure of NCEPOD

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. Each of these bodies nominates members on to NCEPOD's Steering Group.

Steering Group 2018

Dr M Nathanson	Association of Anaesthetists of Great Britain and Ireland
Vacancy	Association of Surgeons of Great Britain and Ireland
Mr K Altman	Faculty of Dental Surgery, Royal College of Surgeons of England
Vacancy	Faculty of Public Health Medicine
Mr S Barasi	Lay Representative
Ms S Payne	Lay Representative
Dr J C Carey	Royal College of Anaesthetists
Dr K Ramachandran	Royal College of Anaesthetists
Dr J Butler	Faculty of Intensive Care Medicine
Vacancy	Royal College of Emergency Medicine
Dr A Tavaré	Royal College of General Practitioners
Dr N Ashby	Royal College of Nursing
Mr T Hillard	Royal College of Obstetricians and Gynaecologists
Mr W Karwatowski	Royal College of Ophthalmologists
Dr I Doughty	Royal College of Paediatrics and Child Health
Dr L Igali	Royal College of Pathologists
Mr M McKirdy	Royal College of Physicians and Surgeons of Glasgow
Dr M Jones	Royal College of Physicians of Edinburgh
Vacancy	Royal College of Physicians of London
Vacancy	Royal College of Physicians of London
Dr J Carlile	Royal College of Psychiatrists
Prof R McWilliams	Royal College of Radiologists
Mr W Tennant	Royal College of Surgeons of Edinburgh
Mr J Abercrombie	Royal College of Surgeons of England

Observers

Dr D Sharpstone	Coroners' Society of England and Wales

Trustees

Mr Ian Martin – Chair | Dr D Mason – Honorary Treasurer
Ms J Barber | Professor T J Hendra

NCEPOD is a company, limited by guarantee
(Company number: 3019382) and a registered charity
(Charity number: 1075588)
Company Secretary Dr M Mason

Clinical Co-ordinators

The Steering Group appoint a Lead Clinical Co-ordinator for a defined tenure. In addition there are 8 Clinical Co-ordinators who work on each study. All Co-ordinators are engaged in active academic/clinical practice (in the NHS) during their term of office.

Lead Clinical Co-ordinator: Dr V Srivastava (Medicine)
Clinical Co-ordinators: Dr K Wilkinson (Anaesthesia)
Dr M Juniper (Medicine) | Dr A P L Goodwin (Anaesthesia)
Mr M Sinclair (Surgery) | Dr S McPherson (Interventional Radiology) | Dr A Michalski (Oncology)

Lay Representatives

NCEPOD has a number of lay representatives who assist in all aspects of NCEPOD's work.
Alice Joy | Ron Newall |Sharon North| Hayley Topping
Nigel Buck | Constantinos Regas

Commissioning and supporting organisations

The Clinical Outcome and Review Programme (CORP) into Medical and Surgical Care is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England, NHS Wales, the Health and Social care division of the Scottish Government, the Northern Ireland Department of Health, Social Services and Public Safety (DHSSPS), the States of Jersey, the Bailiwick of Guernsey, and the Isle of Man.

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King Edward VII's Hospital Sister Agnes | New Victoria Hospital | Nuffield Health | Ramsay Health Care UK
Spire Health Care | St Anthony's Hospital | The Horder Centre | The London Clinic | Ulster Independent Clinic

Members of the Clinical Outcome Review Programme into Medical and Surgical Care Independent Advisory Group:

Rachel Binks | Mike Dent | Mark Ferreira | Margaret Hughes | Donal O'Donoghue | Terence O'Kelly | Joan Russell | David Saunders | Roger Taylor | William Taylor | Phil Willan
Paddy Woods

Members of the HQIP team

Mirek Skrypak | Jill Stoddart | Vivien Seagrove | James Campbell

Appendix 3 – Participation

Trust Name	Clinical data returned	Organisational data returned
Abertawe Bro Morgannwg University Health Board	Yes	Yes
Aintree Hospitals NHS Foundation Trust	N/A	Yes
Alder Hey Children's NHS Foundation Trust	Yes	Yes
Airedale NHS Foundation Trust	N/A	No
Aneurin Bevan University Health Board	N/A	No
Ashford & St Peter's Hospitals NHS Trust	N/A	Yes
Barking, Havering & Redbridge University Hospitals NHS Trust	Yes	Yes
Barts Health NHS Trust	Yes	Yes
Basildon & Thurrock University Hospitals NHS Foundation Trust	Yes	Yes
Belfast Health and Social Care Trust	Yes	Yes
Betsi Cadwaladr University Local Health Board	N/A	Yes
Birmingham Women's and Children's NHS Foundation Trust	Yes	Yes
Blackpool Teaching Hospitals NHS Foundation Trust	N/A	Yes
Bradford Teaching Hospitals NHS Foundation Trust	N/A	Yes
Brighton and Sussex University Hospitals NHS Trust	Yes	Yes
Buckinghamshire Healthcare NHS Trust	Yes	No
Burton Hospitals NHS Foundation Trust	N/A	No
Calderdale & Huddersfield NHS Foundation Trust	N/A	Yes
Cambridge University Hospitals NHS Foundation Trust	Yes	Yes
Cardiff and Vale University Health Board	Yes	Yes
Chelsea & Westminster NHS Foundation Trust	N/A	Yes
City Hospitals Sunderland NHS Foundation Trust	N/A	Yes
Colchester Hospital University NHS Foundation Trust	N/A	Yes
Countess of Chester Hospital NHS Foundation Trust	Yes	Yes
County Durham and Darlington NHS Foundation Trust	N/A	Yes
Croydon Health Services NHS Trust	N/A	Yes
Cwm Taf University Health Board	N/A	Yes
Dartford & Gravesham NHS Trust	N/A	No
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	N/A	Yes
Dorset County Hospital NHS Foundation Trust	N/A	Yes
East Cheshire NHS Trust	N/A	Yes
East & North Hertfordshire NHS Trust	Yes	Yes
East Kent Hospitals University NHS Foundation Trust	N/A	Yes
East Lancashire Hospitals NHS Trust	N/A	Yes
East Sussex Healthcare NHS Trust	Yes	Yes
Epsom and St Helier University Hospitals NHS Trust	N/A	Yes
Frimley Health NHS Foundation Trust	N/A	Yes
Gateshead Health NHS Foundation Trust	N/A	Yes
Great Ormond Street Hospital for Children NHS Trust	Yes	Yes

Appendix 3 – Participation (continued)

Trust Name	Clinical data returned	Organisational data returned
Great Western Hospitals NHS Foundation Trust	Yes	Yes
Guy's & St Thomas' NHS Foundation Trust	Yes	Yes
Hampshire Hospitals NHS Foundation Trust	Yes	Yes
Harrogate and District NHS Foundation Trust	N/A	Yes
Hillingdon Hospitals NHS Foundation Trust	N/A	Yes
Hull and East Yorkshire Hospitals NHS Trust	Yes	Yes
Hywel Dda University Health Board	N/A	Yes
Imperial College Healthcare NHS Trust	N/A	Yes
Ipswich Hospital NHS Trust	Yes	Yes
Isle of Man Department of Health & Social Security	N/A	Yes
Kettering General Hospital NHS Foundation Trust	N/A	Yes
Kingston Hospital NHS Foundation Trust	N/A	Yes
King's College Hospital NHS Foundation Trust	Yes	Yes
Lancashire Teaching Hospitals NHS Foundation Trust	N/A	Yes
Lewisham and Greenwich NHS Trust	Yes	Yes
London North West University Healthcare NHS Trust	Yes	Yes
Luton and Dunstable Hospital NHS Foundation Trust	N/A	Yes
Maidstone and Tunbridge Wells NHS Trust	N/A	Yes
Manchester University NHS Foundation Trust	Yes	Yes
Medway NHS Foundation Trust	Yes	Yes
Mid Cheshire Hospitals NHS Foundation Trust	N/A	Yes
Mid Essex Hospitals NHS Trust	N/A	Yes
Mid Yorkshire Hospitals NHS Trust	N/A	Yes
Milton Keynes University Hospital NHS Foundation Trust	Yes	Yes
Newcastle upon Tyne Hospitals NHS Foundation Trust	Yes	Yes
NHS Ayrshire & Arran	N/A	No
NHS Borders	N/A	No
NHS Dumfries & Galloway	N/A	No
NHS Forth Valley	N/A	Yes
NHS Grampian	Yes	Yes
NHS Greater Glasgow & Clyde	N/A	No
NHS Highland	N/A	Yes
NHS Lothian	N/A	No
NHS Orkney	N/A	No
NHS Tayside	N/A	Yes
North Bristol NHS Trust	N/A	Yes
Northern Devon Healthcare NHS Trust	N/A	Yes
Northern Health & Social Care Trust	N/A	No

Appendix 3 – Participation (continued)

Trust Name	Clinical data returned	Organisational data returned
Northern Lincolnshire & Goole NHS Foundation Trust	N/A	Yes
Norfolk & Norwich University Hospital NHS Trust	Yes	Yes
North Tees and Hartlepool NHS Foundation Trust	N/A	Yes
North West Anglia NHS Foundation Trust	N/A	Yes
North Middlesex University Hospital NHS Trust	N/A	Yes
Northampton General Hospital NHS Trust	Yes	Yes
Nottingham University Hospitals NHS Trust	Yes	Yes
Northumbria Healthcare NHS Foundation Trust	N/A	Yes
Oxford University Hospitals NHS Foundation Trust	Yes	Yes
Pennine Acute Hospitals NHS Trust (The)	No	Yes
Poole Hospital NHS Foundation Trust	No	No
Portsmouth Hospitals NHS Trust	N/A	Yes
Rotherham NHS Foundation Trust	N/A	Yes
Royal Berkshire NHS Foundation Trust	Yes	Yes
Royal Brompton and Harefield NHS Foundation Trust	N/A	Yes
Royal Cornwall Hospitals NHS Trust	No	No
Royal Devon and Exeter NHS Foundation Trust	Yes	Yes
Royal Free London NHS Foundation Trust	N/A	Yes
Royal Liverpool & Broadgreen University Hospitals NHS Trust	Yes	Yes
Royal Surrey County Hospital NHS Trust	N/A	Yes
Royal United Hospitals Bath NHS Foundation Trust	N/A	Yes
Salford Royal Hospitals NHS Foundation Trust	N/A	No
Salisbury NHS FoundationTrust	N/A	Yes
Sandwell and West Birmingham Hospitals NHS Trust	N/A	Yes
Sheffield Children's NHS Foundation Trust	Yes	Yes
Sheffield Teaching Hospitals NHS Foundation Trust	Yes	Yes
Sherwood Forest Hospitals NHS Foundation Trust	N/A	Yes
Shrewsbury and Telford Hospitals NHS Trust	N/A	Yes
South Eastern Health & Social Care Trust	N/A	Yes
Southern Health & Social Care Trust	N/A	Yes
South Tees Hospitals NHS Foundation Trust	Yes	Yes
South Tyneside NHS Foundation Trust	N/A	Yes
South Warwickshire NHS Foundation Trust	N/A	Yes
Southend University Hospital NHS Foundation Trust	Yes	No
St George's University Hospitals NHS Foundation Trust	Yes	Yes
St Helens and Knowsley Teaching Hospitals NHS Trust	N/A	Yes
States of Jersey Health & Social Services	Yes	Yes
Stockport NHS Foundation Trust	N/A	Yes
Surrey & Sussex Healthcare NHS Trust	N/A	Yes

Appendix 3 – Participation (continued)

Trust Name	Clinical data returned	Organisational data returned
Taunton & Somerset NHS Foundation Trust	N/A	Yes
The Christie NHS Foundation Trust	Yes	Yes
The Clatterbridge Cancer Centre NHS Foundation Trust	Yes	Yes
The Dudley Group NHS Foundation Trust	Yes	Yes
The Leeds Teaching Hospitals NHS Trust	Yes	Yes
The Princess Alexandra Hospital NHS Trust	N/A	Yes
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust	N/A	Yes
The Royal Marsden NHS Foundation Trust	Yes	Yes
The Royal Wolverhampton Hospitals NHS Trust	Yes	Yes
The University Hospitals of the North Midlands NHS Trust	N/A	Yes
Torbay and South Devon NHS Foundation Trust	N/A	Yes
United Lincolnshire Hospitals NHS Trust	N/A	Yes
University College London Hospitals NHS Foundation Trust	Yes	Yes
University Hospital Southampton NHS Foundation Trust	Yes	Yes
University Hospitals Birmingham NHS Foundation Trust	Yes	Yes
University Hospitals Coventry and Warwickshire NHS Trust	N/A	Yes
University Hospitals Plymouth NHS Trust	N/A	Yes
University Hospitals of Bristol NHS Foundation Trust	No	Yes
University Hospitals of Leicester NHS Trust	Yes	Yes
University Hospitals of Morecambe Bay NHS Trust	N/A	Yes
Velindre NHS Trust	N/A	Yes
Walsall Healthcare NHS Trust	N/A	Yes
Warrington & Halton Hospitals NHS Foundation Trust	N/A	Yes
West Hertfordshire Hospitals NHS Trust	Yes	Yes
West Suffolk NHS Foundation Trust	N/A	Yes
Weston Area Health Trust	N/A	No
Western Sussex Hospitals NHS Foundation Trust	N/A	Yes
Whittington Health NHS Trust	N/A	Yes
Worcestershire Acute Hospitals NHS Trust	N/A	No
Western Health & Social Care Trust	N/A	Yes
Wirral University Teaching Hospital NHS Foundation Trust	N/A	Yes
Wrightington, Wigan & Leigh NHS Foundation Trust	N/A	Yes
Wye Valley NHS Trust	N/A	Yes
Yeovil District Hospital NHS Foundation Trust	N/A	Yes
York Teaching Hospitals NHS Foundation Trust	N/A	Yes

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