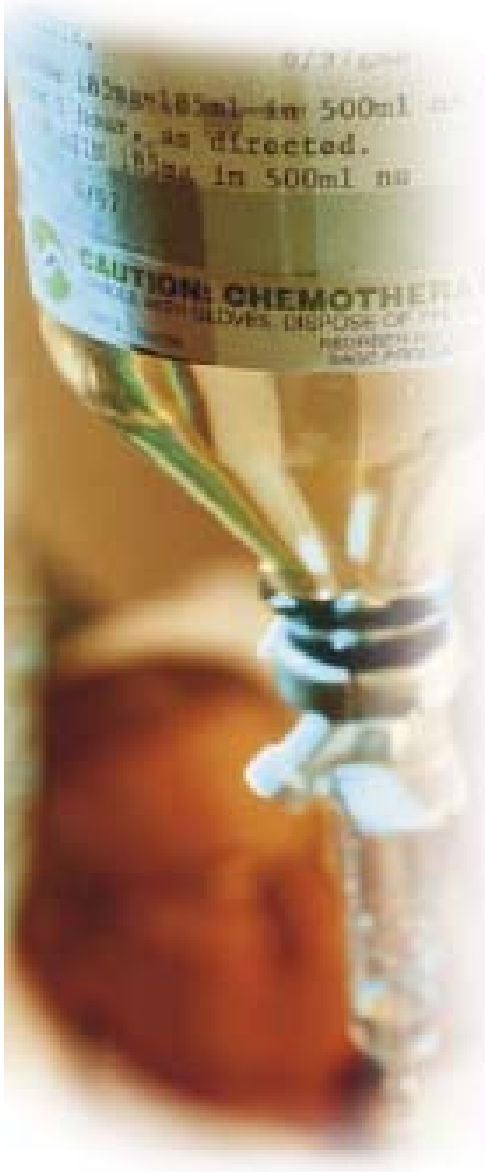
NCEPOD audit pack



For better, for worse?

A review of the care of patients who died within 30 days of receiving systemic anti-cancer therapy

NCEPOD

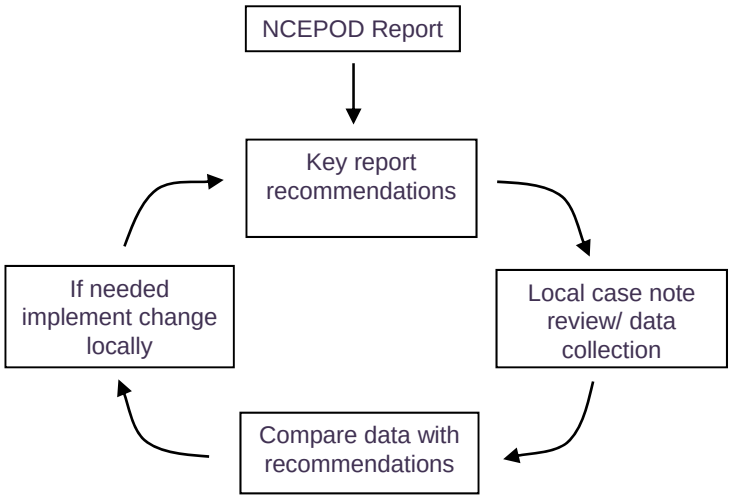
What is clinical audit?

The National Institute for Clinical Excellence (NICE) endorsed definition of clinical audit is: 'A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery'. Please refer to the Health Quality Improvement Partnership (HQIP) www.hqip.org.uk for more details.

NCEPOD – "Improving the quality of medical and surgical care".
The overall aim of NCEPOD is to assist in maintaining and improving standards of medical and surgical care.

This is achieved by undertaking confidential questionnaire and peer review based studies, the findings of which are disseminated back to the medical profession and wider audience in the form of a report. Each NCEPOD report makes a number of key recommendations related to both clinical and organisational aspects of care. It is only when these recommendations are implemented that NCEPOD realises its function and overall aim.

The purpose of the NCEPOD audit pack is to provide clinicians with a tool to carry out local audits based on the findings of specific NCEPOD reports. Where appropriate report recommendations have been adapted to become more relevant to front line clinicians and case note review.



Introduction

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) has performed a study on the use of systemic anti-cancer therapy (SACT) in both palliative and potentially curative clinical management plans. The aim of palliative treatment is to relieve or delay the onset of symptoms. Consequently drug doses are adjusted in order to minimise any treatment related toxicity. In potentially curative treatments, maximum tolerated drug doses are used in order to achieve greater efficacy. However, these treatment regimens can be associated with a greater risk of morbidity and possible mortality.

Potential side effects of treatment include nausea and vomiting, mouth ulceration, diarrhoea, hair loss and bone marrow depression. Treatment related toxicities range in severity and are graded using the Common Toxicity Criteria. Adjustments to the dose and timing of treatment and the prophylactic use of anti-emetics, antibiotics and bone marrow stimulants have resulted in a reduction in the severity of side effects. However, one of the most serious complications of treatment is neutropenic sepsis. Bone marrow depression leads to a reduction in the number of neutrophils in the peripheral blood and the immune system's ability to combat infection. Systemic infection as a result of neutropenia can be life threatening. Patients may also suffer serious complications associated with the route of drug administration, for example, central venous line infections or thromboses and associated life threatening pulmonary emboli.

Throughout this report, the following national clinical guidelines on the management of cancer and the use of SACT have been used as standards where possible:

•The Department of Health's Manual for Cancer Services - chemotherapy section, against which the delivery of the chemotherapy service was assessed during peer review[1];

•The Clinical Oncology Information Network (COIN) project which promotes effective clinical practice in oncology and was sponsored by the Faculty of Clinical Oncology of The Royal College of Radiologists (RCR) and the Joint Collegiate Council for Oncology (JCCO)[2,3];

•Chemotherapy guidelines produced by the British Committee for Standards in Haematology (BCSH)[4];

•The National Institute for Health and Clinical Excellence (NICE) cancer service guidance, clinical guidelines and technology appraisals[5-7].

Although clinical outcomes following treatment of cancer and haematological malignancies are improving, there was concern that the quality of care was not of a consistently high standard across the UK. The Joint Specialty Committee (JSC) of Medical Oncology of the Royal College of Physicians, supported by the JCCO, submitted a cancer study proposal to NCEPOD in February 2005. The topic was selected by the Steering Group and the project commenced in January 2006.

Introduction

NCEPOD studied the death of those patients who died within 30 days of treatment, looking at whether the death was due to treatment related toxicity, progression of malignant disease or an unrelated cause. NCEPOD looked for remediable factors in the process of care in the prescribing and administration of SACT in the clinical care following development of toxicity and the initial decision to treat with SACT. This study also assessed the resources available for the non surgical management of malignant disease, patient information, the use of local clinical care pathways and clinical governance programmes.

The oncology service

The non surgical oncology service is provided by specialist oncologists.

Clinical oncologists are members of the Royal College of Radiologists (Oncology section) who have undergone specialist training in the provision of radiotherapy and chemotherapy.

Medical oncologists are members of the Royal College of Physicians and have specialist training in the management of malignancies using chemotherapy.

Both clinical and medical oncologists are based in cancer centres with peripheral clinics in cancer units. They work together as teams specialising in specific tumour types.

Haemato-oncologists are members of both the Royal College of Physicians and Royal College of Pathologists, who have undergone specialist training in haematology and the management of haematological malignancies. They are usually based within the haematology departments of large teaching and district general hospitals.

This study involved the collation of data on resources and clinical policies within individual hospitals. The presentation of some of the organisational data is related to service provision – clinical/medical oncology or haemato-oncology, as these services are often provided by different units.

All of the study group patients died within 30 days of treatment and therefore the group was not a representative sample of the total population receiving SACT

Method

Study aim
The aim of this study was to examine the process of care of patients who died within 30 days of receiving systemic anti-cancer therapy (SACT) in order to identify remediable factors in the care received by these patients.

Objectives
Six key areas of interest were identified that would address the overall aim of the study:
•The appropriateness of the decision to treat with SACT;
•The process of care in the prescribing and administration of SACT;
•The safety of care in the monitoring of toxicity and managing complications;
•End of life care;
•Communication - patient information, multidisciplinary team (MDT) working, referral pathways;
•Clinical governance, clinical audit and risk
•management issues.

Expert group
An expert group was convened following nominations from relevant Royal Colleges and specialist Societies. The group comprised medical and clinical oncologists, haemato-oncologists, a gynaecological oncologist, a palliative medicine physician, a pharmacist, a specialist chemotherapy nurse, and a patient representative. The members contributed to the preparation of the study protocol and design of data collection forms. The group defined the aims and objectives of the study, reviewed the analyses of the data and commented on the initial drafts of the report.

Independent advice on the study method and data analysis was provided by the Clinical Operational Research Unit (CORU) at University College London (UCL).

Hospital participation
National Health Service hospitals in England, Wales and Northern Ireland were expected to participate, as well as hospitals in the independent sector and 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 liaison between NCEPOD and the hospital staff, facilitating case identification, dissemination of questionnaires and data collation.

Pilot study
To test the feasibility of certain aspects of the study, a pilot study was conducted in September 2006.
This assessed:
• The methods used and the ease of obtaining data;
• The appropriateness of the questionnaires;
• The incidence of deaths within 30 days of SACT.
Twenty six hospitals participated in the pilot study. Hospitals were selected to ensure a range of sizes and types of hospital. Each hospital was asked to complete an organisational questionnaire and comment on the content and format.

The NCEPOD Local Reporter at each hospital was asked to identify all patients treated with SACT between 1st September 2006 and 30th September 2006 and provide data regarding the date of SACT and date of death if applicable.

Method

Within each hospital, two or three cases of patients who had died within 30 days of SACT were chosen by NCEPOD for detailed review. The cases were selected to ensure a range of different tumour types. The local consultants were requested to complete and comment on the clinical questionnaires and the NCEPOD staff used photocopied casenote extracts to undertake a detailed review of the patients' care and assess the ease of completion of the assessment form.

Main study

Study population

Data were collected on patients who were treated with SACT between 1st June 2006 and 31st July 2006 inclusive and on patients who died between 1st June 2006 and 31st August 2006 inclusive.

Inclusion criteria

1. Patients aged 16 years or over; who had
2. Solid tumours or haematological malignancies;

who then

3. Received intravenous, oral, subcutaneous, intravesical, intrathecal, or intraperitoneal chemotherapy, monoclonal antibodies or immunotherapy during the study period; and
4. Who died within 30 days of receiving SACT, either in hospital or in the community.

The 30 day period was defined as 30 days from the first day of the SACT cycle immediately prior to death. When SACT was given continuously, then the 30 day period was defined as death within 30 days of the date of the last prescription.

Exclusion criteria

The following groups of patients were excluded from the study:

- Patients in Phase I trials;
- Patients receiving hormone therapy alone;
- Patients receiving vaccines;
- Patients receiving gene therapy.

Case ascertainment

The following data collection methods were used.

The NCEPOD Local Reporter liaised with the hospital pharmacist to identify patients who received SACT between 1st June 2006 and 31st July 2006 inclusive. The data were entered onto a spreadsheet provided by NCEPOD.

The NCEPOD Local Reporter identified all patients who died within their hospital, regardless of disease type or disorder, between 1st June 2006 and 31st August 2006 inclusive and entered the data onto the same spreadsheet.

An exercise was undertaken by NCEPOD to identify all patients who had died within 30 days of SACT administration. A list of patients who had received SACT but had not died in hospital was supplied to the Office for National Statistics who identified patients who had died out of hospital.

Method

Questionnaires and casenotes

Organisational questionnaire
An organisational questionnaire was sent to every hospital that had informed NCEPOD that SACT was administered on site. Information was collected at hospital level as it gave a better indication of the facilities available for a patient at the location where they were receiving care, rather than all the facilities available within a multi-hospital trust. This questionnaire allowed data to be collected concerning staff numbers, departmental facilities and local clinical care protocols for each participating hospital.

Questionnaire A - Treatment plan and administration
This questionnaire was sent to the consultant responsible for initiating the most recent course of SACT.

Questionnaire B - Follow-up, toxicity and death
For patients who died in hospital, this questionnaire was sent to the consultant responsible for the care of the patient at the time of death.

For patients who died in the community, the questionnaire was sent to the consultant responsible for initiating the most recent course of SACT.

Casenotes
Photocopies of extracts of the medical record were requested. These included:
➢Data related to the most recent course of SACT
➢The complete casenotes for the last 30 days of life:
•Inpatient and outpatient annotations – medical and nursing
•Drug charts
•Observation charts
•Notes from MDT meetings
•Correspondence between health care professionals
•Operation notes
• Pathology results
•Radiology investigation results
•Consent forms for SACT
•Chemotherapy prescriptions
•Radiotherapy prescriptions
•Haematology biochemistry results) for last course of SACT (this may have included a number of cycles)
•Creatinine clearance
•Tumour marker results (CEA, CA 19-9, CA 125, CA 153, PSA, AFP, BHCG)
•Do not attempt resuscitation (DNAR) orders
•End of Life Care Pathway documentation
•Incident report form and details of outcome
•Autopsy report

Assessment form
Key data from the casenotes were extracted by nonclinical staff at NCEPOD and recorded on the assessment form (AF) in order to construct a patient journey. The rest of the form was completed by clinical advisors during their detailed review of each case. Expert opinion on the care provided was recorded.

Method

Advisor groups
A multidisciplinary group of advisors was selected to review the completed questionnaires and casenotes. The group of advisors comprised haemato-oncologists, medical and clinical oncologists, a palliative medicine physician, pharmacists and specialist chemotherapy nurses.

All questionnaires and casenotes were anonymised by the non-clinical staff at NCEPOD. All identifying information relating to the patient, medical staff and hospital were removed. No clinical staff at NCEPOD, nor advisors, had access to any information that would allow patients, clinical staff of hospitals to be identified.

Following anonymisation, each case was reviewed by an oncologist or haemato-oncologist as appropriate, followed by a pharmacist and a nurse. The cases were often very complex and review by three advisors allowed the process to be as thorough as possible. Cases where it was difficult to reach a decision regarding care received were discussed within the group of advisors and a consensus reached.

Quality and confidentiality
Missing casenotes that were essential to the peer review process were requested again if not initially returned to NCEPOD. When the data were as complete as possible, the identifying casenote number (and any other identifiable information) on each questionnaire was removed. Each case was assigned a unique NCEPOD number so that cases could not be easily linked to a hospital.

The data from all the questionnaires and assessment forms were electronically scanned into a preset database. Prior to any analysis taking place, the dataset was cleaned to ensure that there were no duplicate records and that erroneous data had not been entered during scanning. All data were then validated by NCEPOD non-clinical staff.

Data analysis
Quantitative data were analysed using Microsoft Access and Excel by the NCEPOD staff.

The qualitative data collected from the questionnaires were coded according to context. These data were reviewed by NCEPOD clinical staff to identify recurring themes. Some of these have been highlighted within the report using case studies.

The findings of the study were reviewed by the expert group, advisors and the NCEPOD Steering Group prior to publication.

Key findings and recommendations

Data overview

Key findings

The clinical questionnaire return rate was low (63%) despite reminder letters to individual consultants and medical directors. This is below the standard expected for NCEPOD studies.

In 35% of patients who died within 30 days of receiving SACT, care provided was judged as good.

In the advisors' opinion there was room for improvement in the care provided to 49% of patients who died within 30 days of receiving SACT.

In 8% of cases the care provided was less than satisfactory. In the advisors' opinion the care was well below an acceptable standard.

Cancer services managers and clinical directors must ensure that time is made available in consultants' job plans for clinical audit. They must also ensure that the time allocated is used for the defined purpose. (Cancer services managers and clinical directors

Key findings and recommendations

Hospital resources

Key findings

84/557 (15%) patients admitted during the last 30 days of life were not admitted to the organisation where their SACT was administered.

17/286 hospitals where SACT was administered did not have a formal arrangement for access to general medical advice.

12/283 hospitals where SACT was administered did not have a formal arrangement for access to general surgical advice.

6/82 hospitals where SACT was administered that did not have on site Level 3 care had no formal arrangement with another hospital with regard to managing the acutely ill patient following treatment with SACT.

77 hospitals had no palliative care team on site and 81/156 (52%) hospitals had palliative care consultant sessions adding up to less than one full time post.

Hospitals admitting patients with complications of SACT that do not have emergency general medical and surgical services on site should have a formal arrangement with a hospital that can provide these services. (Medical directors)

Hospitals that treat patients with SACT but do not have the facilities to manage patients who are acutely unwell should have a formal agreement with another hospital for the admission or transfer of such patients as appropriate. (Medical directors)

A palliative care service should be available for all patients with malignant disease. (Clinical directors

Key findings and recommendations

Decision to treat

Key findings

86% (557/649) of patients in this study were treated with palliative intent.

14% (92/649) of patients in this study were treated with curative intent.

45% (295/657) of patients who died within 30 days of SACT were receiving second or subsequent line therapy.

21% (122/579) of patients who died within 30 days of SACT had a performance score of 3 or 4 at the time of the decision to commence the most recent course of SACT, i.e. severely debilitated.

In 19% (96/513) of cases the decision to treat with the most recent course of SACT was inappropriate in the advisors' view.

The clinical management plan was discussed at an MDT meeting in only 58% (335/578) of patients who died within 30 days of SACT.

In 14% (44/310) of cases the grade of doctor taking consent was not documented on the consent form.

In 25% (76/310) of cases common toxicity was not recorded on the consent form.

In 48% (150/310) of cases serious toxicity was not recorded on the consent form.

Recommendations

NCEPOD supports the Manual for Cancer Services standard that initial clinical management plans for all cancer patients should be formulated within a multidisciplinary team meeting. The MDT should be responsible for agreeing clinical care pathways, including appropriate chemotherapy regimens, doses and treatment durations. (Clinical directors)

The decision whether or not to advise SACT should be undertaken by a consultant oncologist/haematooncologist after a comprehensive clinical review of the patient. (Clinical directors and consultants)

The decision whether to accept treatment should be made by the patient after they have been fully informed of the potential benefits and toxicities and have had sufficient time to consider their decision and discuss it with their family and carers. (Clinical directors)

There should be greater standardisation of the consent form. The name and grade of doctor taking consent should always be stated on the consent form. (Cancer services managers, clinical directors and medical directors)

Consent must only be taken by a clinician sufficiently experienced to judge that the patient's decision has been made after consideration of the potential risks and benefits of the treatment, and that treatment is in the patient's best interest. (Clinical directors)

Giving palliative SACT to poor performance status patients grade 3 or 4 should be done so with caution and having been discussed at a MDT meeting. (Consultants)

Key findings and recommendations

SACT prescriptions and administration

Key findings

Three hospitals permitted SHO/ST1/2 doctors to initiate a course of SACT.

19 hospitals permitted SHO/ST1/2 doctors to prescribe a second or subsequent cycle of SACT.

Four hospitals allowed junior doctors to prescribe cycles of SACT from the moment of employment, with no assessment of competency or training programme.

52% (304/582) of patients in this study who died within 30 days of receiving SACT, died following cycle 1 of a course of SACT.

Essential pre-treatment investigations were omitted in 14% (64/461) of patients.

There was failure to act upon unacceptable pre-treatment investigations in 65/77 cases.

There was no record of the presence or absence of toxicity following the previous cycle of SACT in 36% (97/267) of cases.

No assessment of tumour response was made in 46% (126/276) of patients.

In only 53% (196/369) of cases was there evidence that a pharmacist had checked the SACT prescription.

In only 71% (146/201) of cases was there evidence that SACT had been checked by two nurses prior to administration.

Recommendations

Junior medical staff at FY1, FY2, ST1 and ST2 grade should not be authorised to initiate SACT. (Clinical directors)

All independent and supplementary prescribers (specialist chemotherapy nurses and cancer pharmacists) and junior medical staff should be locally trained/accredited, following attendance at a supplementary prescribers' course, before being authorised to prescribe SACT. (Cancer services managers and clinical directors)

The results of a pre-treatment full blood count and renal and liver functions tests should be assessed before each cycle of chemotherapy. (Clinical directors)

Toxicity check lists should be developed to assist record keeping and aid the process of care in prescribing SACT. (Cancer services managers and clinical directors)

Assessment of tumour response to treatment should be undertaken and recorded at appropriate intervals depending on the treatment intent and SACT regimen used. (Consultant oncologists and clinical directors)

All SACT prescriptions should be checked by a pharmacist who has undergone specialist training, demonstrated their competence and are locally authorised/accredited for the task. This applies to oral as well as parenteral treatments. (Clinical directors and pharmacists)

Pharmacists should sign the SACT prescription to indicate that it has been verified and validated for the intended patient and that all the safety checks have been undertaken. (Pharmacists)

NCEPOD

Key findings and recommendations

Safety of SACT

Key findings

96% of hospitals provide written information to patients about what to do if they become unwell (247/256 for clinical/medical oncology and 237/248 for haematooncology).

43% (220/514) of cases who died within 30 days of SACT suffered grade 3/4 treatment related toxicity.

1 in 5 hospitals did not have a policy for the emergency admission of patients with SACT toxicity (23% (60/258) clinical/medical oncology and 19% (46/244) for haematooncology).

The last cycle of SACT was given at a reduced dose in 23% (112/479) of cases. In the advisors' opinion a further 13% (46/367) of cases should have had a reduced dose of SACT.

The last cycle of SACT was delayed in 14% (66/479) of cases. In the advisors' opinion a further 14% (58/413) of cases should have had the administration of SACT delayed.

In the advisors' opinion 12% (51/435) of patients continued to receive SACT when there was obvious disease progression.

Recommendations

If the patient has suffered clinically significant grade 3/4 toxicity with the previous cycle of SACT, a dose reduction or the use of prophylactic GCSF should be considered depending on the treatment intent. (Consultants and clinical directors)

Consultants should follow good clinical practice and consider:

- Reducing the dose of SACT in patients
  a) that have received a number of previous courses of treatment
  b) that have a poor performance status
  c) that have significant co-morbidity;
- Reducing the dose of or omitting drugs excreted via the kidney, if the patient has impaired renal function;
- Reducing the dose of or omitting drugs excreted via the liver, if the patient has impaired liver function. (Consultants and clinical directors)

NCEPOD

Key findings and recommendations

Hospital admissions during the last 30 days of life

Key findings

239/557 (42%) patients were admitted to general medicine following a SACT complication rather than to oncology/haemato-oncology specialists.

17/281 (6%) hospitals had no policy for the management of neutropenic sepsis.

17% (43/250) of patients who had a grade 3/4 event delayed seeking advice for at least 24 hours.

Recommendations

A debate within the profession is needed to explore whether it is appropriate that patients treated with SACT should be admitted under general medicine if problems occur. Any substantial change would require expansion of the oncology workforce. An alternative would be a strengthening of links between oncology and general medicine to ensure protocols and training are in place for the management of complications of SACT. (Medical directors, cancer services managers and clinical directors)

Emergency admissions services must have the resources to manage SACT toxicity. These should include:

- A clinical care pathway for suspected neutropenic sepsis;
- A local policy for the management of neutropenic sepsis;
- Appropriately trained staff familiar with the neutropenic sepsis policy;
- The policy should be easily accessible in all emergency departments;
- Availability of appropriate antibiotics within the emergency department. (Cancer services managers and clinical directors)

In planning the provision of oncology services outside of cancer centres, commissioners should take into account the need for specialist advice to be readily available when patients are admitted acutely. (Cancer services managers)

NCEPOD

Key findings and recommendations

End of life care

Key findings

In 27% (115/429) of cases the advisors believed that the SACT had caused death or hastened death.

Cases of neutropenic sepsis in patients with solid tumours were audited in only 45% (101/224) hospitals and in haematological malignancies it was audited in 51% (100/196).

Medical and clinical oncologists audited deaths within 30 days of SACT in only 47 hospitals and haematooncologists audited deaths within 30 days in only 24 hospitals.

Only 16% (76/485) of cases who died within 30 days of SACT were discussed at a morbidity and mortality meeting.

Recommendations

A pro-active rather than reactive approach should be adopted to ensure that palliative care treatments or referrals are initiated early and appropriately. Oncologists should enquire at an appropriate time, about any advance decisions the patient might wish to make should they lose the capacity to make their own decisions in the future. (Consultants)

Regular clinical audit should be undertaken on the management of all cases of neutropenic sepsis following the administration of SACT. The process of care should be compared to standards agreed by the cancer network. Cancer centres and cancer units should collaborate in undertaking these audits. (Clinical directors)

All deaths within 30 days of SACT should be considered at a morbidity and mortality or a clinical governance meeting. (Clinical directors and consultants)

NCEPOD

References

1. Manual for cancer services. 2004. Department of Health. London http://www.dh.gov.uk/en/Healthcare/National Service Frameworks/Cancer/DH_4135595

2. Chemotherapy Guidelines: Clinical Oncology Information Network (COIN). Royal College of Radiologists. http://www.rcr.ac.uk

3. Principles to underpin the delivery of radiotherapy and chemotherapy services to NHS cancer patients The Joint Collegiate Council for Oncology February 2007 www.rcr.ac.uk/docs/oncology/pdf/Principlestounderpin.pdf

4. Guidelines on the Management of Acute Myeloid Leukaemia in Adults (2005). British Committee for Standards in Haematology (BCSH). British Society for Haematology. http://www.b-s-h.org.uk/

5. Cancer Service Guidance: Improving Outcomes in Cancer. National Institute for Health and Clinical Excellence. http://www.nice.org.uk/

6. Guidance on the use of ultrasound locating devices for placing central venous catheters Technology Appraisal No. 49 Issue date: September 2002 www.nice.org.uk/nicemedia/pdf/Ultrasound_49_GUIDANCE.pdf

7. Improving Outcomes in Haematological Cancers The Manual Published by the National Institute for Clinical Excellence October 2003 ISBN:1-84257-398-5 http://www.nice.org.uk/nicemedia/pdf/NICE_HAEMATOLOGICAL_CSG.pdf

NCEPOD