SYSTEMIC ANTI-CANCER THERAPY STUDY

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

QUESTIONNAIRE B: Follow-up, Toxicity and Death

CONFIDENTIAL

Hospital number of patient: | | | | | | | | | | | | | | | |

Name of NCEPOD Local Reporter: _____

Specialty of doctor completing form: _____

What is this study about?

NCEPOD is examining the process of care of all patients who die within 30 days of systemic anti-cancer therapy (SACT), looking for areas where their care could have been improved. Please see "Definitions" on page 3. The study will not concentrate solely on those patients whose death may have been treatment-related.

This work is supported by the **Joint Collegiate Council for Oncology (JCCO)**, a joint group between the Royal College of Radiologists and Royal College of Physicians; and the **Joint Specialty Committee (JSC) for Medical Oncology** at the Royal College of Physicians.

Who should complete this questionnaire?

Questionnaire B – Follow-up, Toxicity and Death

a) If the patient died in hospital - the consultant responsible for the patient **at time of death** OR

b) If the patient died in the community and **had not been admitted as an inpatient** between the SACT date identified on this covering letter and death - the Consultant Clinical Oncologist, Medical Oncologist, Haemato-oncologist, or other clincian responsible for **initiating the most-recent course of SACT.** OR

c) If the patient died in the community and **had been admitted as an inpatient** between the SACT date identified on this covering letter and death - the Consultant who was responsible for the patient **at the time of discharge** from your hospital/centre/stand-alone unit.

To ensure confidentiality of the data, completed questionnaires must be returned directly to NCEPOD, and not via your NCEPOD Local Reporter, or clinical audit department etc.

A copy **must not** be kept in the patient's notes.

Please return completed questionnaires to NCEPOD in the SAE provided.

How to complete this questionnaire

Information will be collected using two methods: Box cross and free text, where your clinical opinion will be requested.

This form will be electronically scanned. Please use a black or blue pen. Please complete all questions with either block capitals or a bold cross inside the boxes provided e.g.

Does this hospital administer SACT to patients as:

☒ Inpatients ☐ Outpatients

If you make a mistake, please "black-out" the incorrect box and re-enter the correct information, e.g.

■ Inpatients ☒ Outpatients

Unless indicated, please mark only one box per question.

A list of definitions is provided on page 3. Should you wish to make any additional comments, space is also provided at the end of the questionnaire.

Incomplete, or non-returned questionnaires will be followed up with your medical director.

Questions or help

If you have any queries about the study or this questionnaire, please contact NCEPOD at

Email: cancertherapies@ncepod.org.uk

Telephone: 020 7631 3444

Thank you for taking the time to complete this questionnaire. The findings of the full study will be published in late 2008.

FOR NCEPOD USE ONLY | | | | | | |

1 850135 358496

This page has been left intentionally blank

Specific inclusions:

1. Patients aged 16 years or over.
2. Suffering from:-
   - Solid malignant tumours, or
   - Haematological malignancies where chemotherapy-based treatments are given including:

   a. Acute leukaemias (acute lymphoblastic and acute myeloid); and

   b. Aggressive but curable lymphomas (including diffuse large cell, Hodgkin's lymphoma, lymphoblastic lymphoma and Burkitt's lymphoma); and

   c. Haematological conditions where treatment is essentially non-curative and aimed at controlling the disease i.e. myeloma, chronic leukaemias, low grade lymphomas, myelodysplastic syndrome and myeloproliferative disease.

3. Who have received intravenous, oral, subcutaneous, intravesical, intrathecal, or intraperitoneal chemotherapy, monoclonal antibodies, or cytokines; and
4. Who have died within 30 days of receiving systemic anti-cancer therapy.

The 30 day period will be defined as 30 days from Day 1 of the SACT cycle immediately prior to death. If SACT is given continuously - 30 days from the date of the last prescription.

Specific exclusions:

- Vaccines
- Gene therapy
- Hormone therapy alone
- Patients in Phase I trials, or trials where clinicians are blinded to the drug being administered to the patient.
- Patients aged <16 years old.

DEFINITIONS

Adverse Events	An unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalisation, or to temporary or permanent impairment, or disability to the patient.
ICU/ITU	An area to which patients are admitted for treatment of actual or impending organ failure, especially when mechanical ventilation is necessary.
Grade 3/4 Toxicity	Please see Appendix I.
Haemato-Oncology	Haematologists specialising in treatment of haematological malignancies.
HDU	High dependency unit beds that are available if need be to patients treated with SACT. A high dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than can be provided on a general ward. It would not normally accept patients requiring mechanical ventilation, but could manage those receiving intensive monitoring.
Medical assessment unit (MAU)	A dedicated unit or ward in which medical patients undergo rapid and rigorous assessment and initial treatment with the purpose of establishing their need for admission to or discharge from hospital.
Oncology	Medical oncology and clinical oncology.
Systemic Anti-Cancer Therapy (SACT)	To include all "traditional" cytotoxics - intravenous, oral, subcutaneous, intravesical, intrathecal, or intraperitoneal chemotherapy, monoclonal antibodies, or cytokines, but excluding vaccines, gene therapy and hormonal agents.

A. PATIENT DETAILS

1. Age at time of death: ☐☐☐ years ☐ Unknown

2. Gender: ☐ Male ☐ Female

3. Primary site of tumour, or type of haematological malignancy: ☐ Unknown

4. Was the patient admitted to hospital during the last 30 days of life? ☐ Yes ☐ No

If YES, go to SECTION B.

If NO, go to SECTION C.

B. THE ADMISSION

5. What was the date of admission? ☐☐ ☐☐ ☐☐

d d m m y y

6. a. Was the admission:

☐ A planned admission

☐ An emergency admission

☐ Unknown

b. What was the reason for the admission?

6. c. To which inpatient specialty was the patient first admitted?

- ☐ Oncology
- ☐ Haematology
- ☐ General medicine
- ☐ General surgery
- ☐ Palliative care
- ☐ MAU
- ☐ Direct to ICU/ITU/HDU
- ☐ Unknown
- ☐ Other *(Please specify)*

7. a. Was this specialty appropriate for the patient's clinical condition? ☐ Yes ☐ No

b. If NO, please provide brief details as to why not:

8. a. Were there any delays in the admission process? ☐ Yes ☐ No ☐ Unknown

b. If YES, please provide a brief list of details:

9. a. Were there any delays in undertaking/reporting of investigations? ☐ Yes ☐ No ☐ Unknown

b. If YES, please provide a brief list of examples:

10. a. Were any essential investigations omitted? ☐ Yes ☐ No ☐ Unknown

b. If YES, please provide a brief list of examples:

11. a. Which **other** specialties were involved in the care of the patient from the inpatient admission until death?
(Please select all that apply)

- ☐ Oncology
- ☐ General medicine
- ☐ Surgery *(Please specify)*
- ☐ Haematology
- ☐ Palliative medicine
- ☐ Other *(Please specify)*
- ☐ None
- ☐ Unknown

If the patient was not admitted under the care of an oncologist/haemato-oncologist:

12. a. Was the Oncologist/Haemato-oncologist informed of the patient's admission? ☐ Yes ☐ No ☐ Unknown

b. How soon after admission in days? ☐☐ days ☐ Unknown

c. How soon after admission was the patient reviewed by the Oncology/Haemato-oncology team during admission?

- ☐ <12 hours
- ☐ 12 -<24 hours
- ☐ 24 - <48 hours
- ☐ 2-7 days
- ☐ >7 days
- ☐ Not seen by the Oncology/Haemato-oncology team during admission

d. Was the patient transferred to an oncologist/haemoto-oncologist? ☐ Yes ☐ No ☐ Unknown

e. If YES, what was the interval between admission and transfer? *(Please specify in hours/days)* ☐☐ ☐☐ ☐ Unknown

d d h h

If the patient was admitted under the care of an oncologist/haemato-oncologist:

f. How soon after admission was the patient reviewed by the consultant?

- ☐ <12 hours
- ☐ 12 -< 24 hours
- ☐ 24 - <48 hours
- ☐ 2-7 days
- ☐ >7 days
- ☐ Not seen by the consultant during admission

13. Please describe in chronological order the ward transfers that this patient undertook
e.g. A&E -> Radiology -> A&E -> MAU -> Medical Ward -> Palliative Care Unit -> Home (with death in the community)
and comment on their appropriateness.

C. COMPLICATIONS DUE TO MOST-RECENT CYCLE OF SACT

14. a. Did the patient suffer any NCI grade 3/4 toxicity related to the most-recent **cycle** of SACT? *(See Definitions)*

☐ Yes ☐ No ☐ Unknown

14. b. If YES, please select all that apply:

- ☐ Neutropaenia
- ☐ Febrile Neutropaenia
- ☐ Infection *(Please specify)* _____
- ☐ Thrombocytopaenia
- ☐ Any thromboembolic complication
- ☐ Haemorrhage
- ☐ Renal impairment
- ☐ Liver impairment
- ☐ Multi organ failure
- ☐ Hypokalaemia
- ☐ Hypomagnesaemia
- ☐ Hypercalcaemia
- ☐ Stomatitis
- ☐ Vomiting
- ☐ Diarrhoea
- ☐ Arrhythmia
- ☐ Myocardial ischaemia
- ☐ Anaphylactic reaction
- ☐ Tumour lysis syndrome
- ☐ Other *(Please specify)* _____

15. a. After becoming unwell, did the patient:

Ring the emergency chemotherapy helpline for advice?	☐ Yes	☐ No	☐ Unknown
Contact general practitioner	☐ Yes	☐ No	☐ Unknown
Attend A&E	☐ Yes	☐ No	☐ Unknown
Other *(Please specify)*	☐ Yes	☐ No	☐ Unknown

_____

b. If the patient called the chemotherapy helpline for advice, was the call logged? ☐ Yes ☐ No ☐ Unknown

c. Was the patient seen within 24 hours by a:

General practitioner	☐ Yes	☐ No	☐ Unknown
Chemotherapy nurse	☐ Yes	☐ No	☐ Unknown
Oncologist/haemato-oncologist	☐ Yes	☐ No	☐ Unknown

16. If the patient was not admitted, please comment on the advice given, investigations undertaken and the management plan:

17. Please select all interventions which to your knowledge occurred after, or during, the most-recent **cycle** of SACT:

- ☐ None
- ☐ Unknown
- ☐ Endoscopy
- ☐ Drainage of ascites
- ☐ Anticoagulation
- ☐ Drainage of pleural effusions
- ☐ Central line placement/replacement
- ☐ Dental treatment
- ☐ Stent placement
- ☐ Surgery *(Please specify)*
- ☐ Other *(Please specify)*

Additional Comments:

18. Please provide a brief clinical summary of the patient's care since the most-recent **cycle** of SACT:

D. PATIENT'S DEATH:

17. Date of death:

d	d	m	m	y	y

18. Where did the death occur? *(Please select one):*

- ☐ Haematology/oncology ward
- ☐ General medical ward
- ☐ General surgical ward
- ☐ ICU/ITU/HDU
- ☐ Palliative care ward
- ☐ In a hospice
- ☐ At home
- ☐ Other *(Please specify)* _____
- ☐ Unknown

19. Was the death of the patient due to: *(Please select all that apply)*

- ☐ Progression of disease
- ☐ Complication of SACT *(Please specify)* _____
- ☐ Other *(Please specify)* _____

20. a. What was recorded on the death certificate?

Ia. _____

Ib. _____

Ic. _____

II. _____

b. Was a post mortem held? ☐ Yes ☐ No ☐ Unknown

6 850135 359245

21. Was the patient's death discussed at an audit or morbidity and mortality meeting? ☐ Yes ☐ No ☐ Unknown

22. a. Were there any adverse events that may have contributed to the patient's death? ☐ Yes ☐ No ☐ Unknown
(See Definitions)

b. If YES, please specify:

E. STRUCTURED COMMENTARY

23. Please outline any organisational aspects of SACT in your hospital that may have had a negative effect on patient outcome following SACT administration (which may have been administered at a different hsopital/centre/stand-alone unit):

24. With the benefit of hindsight, is there anything that you believe could have been done differently regarding the management of this patient? We have highlighted some areas that you may want to consider with respect to patient outcome.

- *Management of toxicity*
- *Management of progressive disease*
- *Follow-up after SACT*
- *Management of co-morbidities*

G. GENERAL COMMENTS

25. Please write clearly any additional observations you wish to report:

Please supply a copy of the following case note extracts for this patient:

TIME PERIOD: LAST 30 DAYS OF LIFE.
(Case notes of entire patient history not required)

- ✔ Notes from MDT meetings.
- ✔ Inpatient and outpatient annotations and correspondence for all **cycles** of the most-recent **course** of SACT between healthcare staff including general practitioners.
- ✔ Haematology (FBC), biochemistry results (LFT, U&E).
- ✔ Radiology investigation results.
- ✔ Tumour marker results (CEA, Ca 19-9, Ca 125, Ca 153, PSA, AFP, BHCG).
- ✔ Drug chart.
- ✔ Observation charts e.g. TPR and fluid balance charts.
- ✔ Any operating notes.
- ✔ Do Not Attempt Resuscitation (DNAR) Statement.
- ✔ End of Life Pathway.
- ✔ Incident Report Form and details of outcome.
- ✔ Post Mortem Report.

We will accept **print outs** directly from your hospital systems for blood/pathology/radiology results etc., but we would still need copies of the case notes where there are **annotations.**

If this was not the hospital where the patient received their most-recent SACT, we will also need **ICD-10 codes** from your hospital systems for all admissions of the patient during the **last 30 days of life. These should be available from your NCEPOD Local Reporter, or Clinical Audit department.**

The questionnaires and associated case note extracts will be anonymised before being reviewed by a multidisciplinary group of clinicians and aggregated data analysed quantitively.

Thank you for your help.

This page has been left intentionally blank

NCEPOD
PO Box 5662
London
W1A 5HD