



# SYSTEMIC ANTI-CANCER THERAPY STUDY

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

## QUESTIONNAIRE A: Treatment Plan & Administration CONFIDENTIAL

Hospital number of patient: 

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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 2. 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 A: Treatment Plan & Administration**  
The questionnaire should be completed by the consultant clinician (e.g. consultant clinical oncologist, medical oncologist, haemato-oncologist or other clinician) responsible for **initiating** the most-recent course of SACT.

**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 2. Should you wish to make 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

Telephone: cancertherapies@ncepod.org.uk

Email: 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 

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### 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

<b>ICU/ITU</b>	An area to which patients are admitted for treatment of actual or impending organ failure, especially when mechanical ventilation is necessary.
<b>Haemato-oncologist</b>	Haematologist specialising in treatment of haematological malignancies.
<b>HDU</b>	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.
<b>Medical assessment unit (MAU)</b>	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.
<b>Oncology</b>	Medical oncology and clinical oncology.
<b>Response to treatment</b>	CR - Complete response PR - Partial response SD - Stable disease PD - Progressive disease Please see Appendix I
<b>Systemic Anti-Cancer Therapy (SACT)</b>	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.

## TREATMENT INTENT DEFINITIONS

<b>Neoadjuvant</b>	SACT prior to surgery and/or radiotherapy.
<b>Adjuvant</b>	SACT following surgery where tumour has been completely resected and there is no evidence of metastatic disease.
<b>Potentially Curative</b>	SACT given with intent to cure.
<b>High Dose Palliative</b>	Where SACT is not necessarily curative but remissions can last years.
<b>Palliative</b>	SACT aimed at symptom control, quality of life improvement, tumour growth restraint, or increased survival times.



## PERFORMANCE SCORES

### ECOG/WHO/Zubrod score

- |   |   |
|---|---|
| 0 - Asymptomatic                            | 3 - Symptomatic, >50% in bed, but not bed bound |
| 1 - Symptomatic but completely ambulant     | 4 - Bed bound                                   |
| 2 - Symptomatic, <50% in bed during the day | 5 - Dead  |

### Karnofsky Performance Status Scale Definitions Rating (%) Criteria

100	Normal no complaints; no evidence of disease.
90	Able to carry on normal activity; minor signs or symptoms of disease.
80	Normal activity with effort; some signs or symptoms of disease.
70	Cares for self; unable to carry out normal activity or to do active work.
60	Requires occasional assistance, but is able to care for most of their personal needs.
50	Requires considerable assistance and frequent medical care.
40	Disabled; requires special care and assistance.
30	Severely disabled; hospital admission is indicated although death not imminent.
20	Very sick; hospital admission necessary; active supportive treatment necessary.
10	Moribund; fatal processes progressing rapidly.
0	Dead.

## COURSES VERSUS CYCLES:

Patients may receive a number of different courses of chemotherapy; each one consisting of several cycles. For example, one course of treatment could consist of six, three-weekly cycles e.g.

Course	Regimen	Cycle	Start Date
1	Capecitabine	1	01/01/05
		2	22/01/05
		3	12/02/05
		4	05/03/05
2	Oxaliplatin, 5FU	1	01/08/05
		2	15/08/05
		3	29/08/05
		4	12/09/05
		5	29/09/05
		6	13/10/05
3	Irinotecan, 5FU	1	01/01/06



## A. PATIENT DETAILS

Immediately prior to commencing most-recent course of SACT:

1. Age  years

2. Gender  Male  Female

3. Ethnic group

### White

British

Other White *(Please specify)*

### Black or Black British

Caribbean

African

Other Black *(Please specify)*

### Mixed

White & Black Caribbean

White & Black African

White & Asian

Other Mixed Ethnic *(Please specify)*

### Asian or Asian British

Indian

Pakastani

Bangladeshi

Other Asian *(Please specify)*

### Chinese or other Oriental

Chinese

Other Oriental *(Please specify)*

### Other

*(Please specify)*

Unknown

## B. PAST MEDICAL HISTORY

4. Please list any past medical history not related to this cancer:

Condition	Date		
	d	m	y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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5. a. Has the patient undergone surgery as part of their treatment for this malignancy?  Yes  No  Unknown

b. If YES, please give details:

Date: d d m m y y

Surgery:

6. a. Has the patient received radiotherapy as part of their treatment for this malignancy?  Yes  No  Unknown

b. If YES, please specify the following:

Date of first fraction	Site	Dose in Gy	No. of Fractionations	Duration in days
d d m m y y				
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input style="width: 100%;" type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
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c. Was radiotherapy given concurrently with this most-recent **course** of SACT?  Yes  No  Unknown

7. a. Has this patient had previous **courses** of SACT for current or other cancer?  Yes  No  Unknown



7. b. If YES, please supply details of all courses given, in this table, making clear the number of lines of treatment and number of cycles: e.g. OxMdG, 15/04/03, 6 cycles, PR

Regimen	Start date of course					No. of cycles completed	Response to Treatment (See Definitions)
	d	d	m	m	y		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### C. MEDICAL CONDITION IMMEDIATELY PRIOR TO MOST-RECENT COURSE OF SACT

#### FOR SOLID TUMOURS & LYMPHOMAS:

8. a. Please state primary site of tumour:

Unknown

b. Please select the **known** site/s of disease when this **course** of SACT started (Please select all that apply)

No macroscopic disease

Primary Site

Lymph nodes (Please specify sites)

Metastases (Please specify sites)

Other (Please specify)

Unknown



**FOR OTHER HAEMATOLOGICAL MALIGNANCIES:**

9. Please state the type:

10. Performance score immediately prior to the most-recent **course** of SACT: *(See Definitions)*

WHO/ECOG  0  1  2  3  4  5 **AND/OR** KPS  %  
 Unknown

11. Please state any co-morbidities:

Ischaemic heart disease

Diabetes mellitus

Other *(Please specify)*

Unknown

12. Medical complications of cancer:

Hypoalbuminaemia

Renal failure

Liver failure

Ascites

Pleural effusion

Spinal cord compression

Other *(Please specify)*

Unknown



13. a. Height   ft   in OR    cm  Unknown

b. Weight    lbs OR    .   kg  Unknown

c. Body surface area (m<sup>2</sup>)  .   m<sup>2</sup>  Unknown

## D. MANAGEMENT PLAN

14. a. Please provide details of the most-recent planned **course** of SACT:

Regimen:

Drugs	Method of Calculation	
	Target doses (mg/m <sup>2</sup> )	AUC
<input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>

b. Cycle length:   days (e.g. 28)

c. Number of cycles planned:

d. Number of cycles given:





15. Tick the box that best describes your SACT treatment intent: *(See Definitions)*

- Neoadjuvant
- Adjuvant
- Potentially Curative
- High Dose Palliative
- Palliative
- Unknown

16. What is your estimated chance of cure in this patient?

- >50%
- 20-49%
- <20%
- 0%

17. a. Was this course of SACT agreed at an MDT meeting?

- Yes
- No
- Unknown

b. What was the grade of doctor who initiated and who prescribed this course of SACT?

	Initiator <i>(Tick one box)</i>	Prescribers <i>(Tick all that apply)</i>
Consultant	<input type="checkbox"/>	<input type="checkbox"/>
Associate Specialist	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Assistant	<input type="checkbox"/>	<input type="checkbox"/>
Medical/Clinical Researcher/Fellow	<input type="checkbox"/>	<input type="checkbox"/>
Staff Grade	<input type="checkbox"/>	<input type="checkbox"/>
SPR/ST3 or higher	<input type="checkbox"/>	<input type="checkbox"/>
SHO/ST1-2	<input type="checkbox"/>	<input type="checkbox"/>
Other <i>(Please specify)</i>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="text"/>	<input type="text"/>
Unknown	<input type="checkbox"/>	<input type="checkbox"/>



18. a. Is there a local written clinical care pathway for the management of this malignancy?  Yes  No  Unknown

b. If YES, was this care pathway followed?  Yes  No

c. If NO, please state reason as to why not:

19. a. Was this course of SACT given as part of a research study?  Yes  No  Unknown

b. If YES, was this: *(Please select all that apply)*

- A single-centre trial
- A multi-centre trial
- A National Cancer Research Network (NCRN) approved trial
- An industry-sponsored trial
- Unknown

## E. MOST-RECENT CYCLE OF SACT GIVEN

Please provide details of the most-recent **cycle** of SACT:

20. a. Cycle number:



20. b. Date of decision to treat:

d	d	m	m	y	y

c. Date: Day 1 of administration

d	d	m	m	y	y

20. d. Drugs	Dose (mg/m <sup>2</sup> )	AUC	Calculated Full Dose(mg)	Dose given(mg)	Percentage Full dose													
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20. e. Was this treatment:

Given as planned

Delayed (Please state reason)

--

Dose reduced (Please state reason)

--



21. Who prescribed this **cycle** of SACT? *(Please select one)*

- Consultant
- Associate Specialist
- Clinical Assistant
- Medical/Clinical Researcher/Fellow
- Staff Grade
- SPR/ST3 or higher
- SHO/ST1-2
- Chemotherapy Nurse (all grades)
- Pharmacist (all grades)
- Other *(Please specify)*
  
- Unknown

22. Who reviewed the patient on the **day of SACT treatment**? *(Please tick all that apply)*

- Consultant
- Associate Specialist
- Clinical Assistant
- Medical/Clinical Researcher/Fellow
- Staff Grade
- SPR/ST3 or higher
- SHO/ST1-2
- Chemotherapy Nurse (all grades)
- Pharmacist (all grades)
- Other *(Please specify)*
  
- No one
- Unknown



23.

Please list all non-SACT medication that has been given as an integral part of the most-recent **cycle** of SACT including I.V. fluids, steroids, anti-emetics:

24.

Where was the most-recent **cycle** of SACT administered? *(Please select one)*

**Day Cases**

- Outpatient clinic
- Day care unit
- Designated chemotherapy unit

**Inpatients**

- Chemotherapy ward
- Oncology ward
- Haematology ward

- 
- Patient's home
  - Unknown
  - Other *(Please expand upon your answer)*

- 25. a. Was the patient instructed regarding measurement of daily body temperature?  Yes  No  Unknown
  
- b. Was the patient provided with a thermometer?  Yes  No  Unknown
  
- c. Was the patient warned of the importance of contacting a doctor immediately if they developed a fever?  Yes  No  Unknown



## F. STRUCTURED COMMENTARY

27. Please outline any organisational aspects of SACT in your hospital that may have had a negative effect on patient outcome:

28. 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 might want to consider with respect to patient outcome.

- *Decision to treat with SACT*
- *Consent to SACT treatment*
- *Administration of SACT*
- *Patient information given*
- *Prescribing of SACT*



## G. GENERAL COMMENTS

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

Please supply copies of the following case note extracts with your questionnaire:

**TIME PERIOD: ALL DATA RELATED TO MOST-RECENT COURSE OF SACT**

**(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 practitioner.
- ✓ Consent form for SACT.
- ✓ Chemotherapy prescriptions.
- ✓ Radiotherapy prescriptions.
- ✓ Haematology (FBC), biochemistry results (LFT, U&E) for the **last two cycles** of SACT and until death.
- ✓ EDTA creatinine clearance prior to last course of SACT.
- ✓ Tumour marker results (CEA, Ca 19-9, Ca 125, Ca 153, PSA, AFP, BHCG).
- ✓ Radiology investigation results.
- ✓ Any operating notes for surgery undertaken within 6 months of commencing the most-recent **course** of SACT, or during the course.
- ✓ Incident Report form and details of outcome.

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**.

**We will also need the ICD-10 codes from your hospital systems for all admissions of this 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 quantitatively.

**Thank you for your help.**





NCEPOD  
PO Box 5662  
London  
W1A 5HD

