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National Chemotherapy Board

Morbidity and Mortality within 30-Days of Systemic Anti-Cancer Therapy (SACT): Review of Current Practice suggested Standardised Review Process May 2016

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Introduction

The importance of having morbidity and mortality (M+M) meetings to review deaths within 30-days of systemic anti-cancer therapy (SACT) has been established. Most Trusts within the UK have developed their own systems for deciding which cases to discuss.

Information on patients who have died within 30-days of SACT is available within the National SACT database for patients treated in England, and can be interrogated to provide the list of cases requiring review for those centres that upload data to it.

The National Chemotherapy Board recognised that while there are many examples of good practice, there is inconsistency of approach between centres which may limit sharing of learning. As part of the workplan of the National Chemotherapy Board the aim was to develop an operational policy and standardised template for use. The approach was to build on the good practice which has been developed to date. In August 2015, senior clinicians involved in 30-day mortality from SACT were asked to share their current Trust documents with the membership of the ACP/JSC, JCCO, RCR, RCPATH, UKCONS, BOPA and patient representative (the constituent organisations of the National Chemotherapy Board).

Responses to the request for information were received from England, Scotland, Wales and Northern Ireland (Appendix 1):

- 18 sites SOPs/information regarding details of M+M meetings
- 24 review proformas reviewed

Review of SOPs and mortality meeting details

- Many examples of well-established, robust and thorough M+M review processes and meetings.
- Some expressed that there are shortfalls in their current practice and this is an area of on-going work, highlighting specific challenges they were encountering.
- Wide variation of practice including responsible staff, frequency of meetings, case selection and case review process.
- Many good practices noted including:
 - Multidisciplinary membership
 - Consideration given to maximising accessibility e.g. rolling rotas or protected staff time
 - Wide range of cases discussed, not only deaths within 30 days of SACT. Examples include deaths within 30, 90 days of radiotherapy, unexpected inpatient deaths, ICU admissions, critical incidents. Some sites are more pro-active about exploring non-hospital deaths of patients on SACT e.g. GP letter requesting information.
 - Non-critical environment encouraged – many instances of any member of staff being able to highlight cases for discussion.
 - Couple of examples (although in the minority, ~3) of independent senior review of **case notes**, either prior to M+M meeting discussion for selected cases where there was felt to be deficiencies in care/lessons to be learnt/SACT felt to have contributed to death or team meetings reviewing case notes together.
 - Record of meeting outcomes and actions accessible to staff/circulated.
 - Meeting outcomes audited or reported to clinical governance meetings.

Review of proformas

- Again wide variation of formats and tools collecting different levels of case detail.
- Many completed online and some linked with e.g. chemotherapy prescribing systems allowing prepopulated fields.
- Varying degrees of closed questions versus open questions/free text. Most reasonably short - 1 to 2 pages.
- Significant differences in number of oncology/haematology specific questions compared with generic questions used to review all inpatient deaths.
- Different sites placed their focus on different aspects of patient care – e.g. safe and effective use of SACT close to death versus review of terminal hospital admission versus end of life care.
- Proformas were reviewed to highlight common areas of data collection. This information obviously facilitates subsequent discussion at a mortality meeting or sometimes is a reflection of the outcomes of a discussion.
- Initially proformas reviewed to see which elements of the NCEPOD SACT audit data collection tool kit were being incorporated. It was felt this provided a good structure for assessing the appropriate and safe use of SACT and correct management of SACT toxicity.

NCEPOD SACT Audit data collection tool kit

(% of proformas specifically asking for this information; for some sites the information below would potentially be captured in case summaries etc provided)

- A. Patient details including primary tumour site and SACT details
(some sites collected information specifically on whether the patient was on a clinical trial and place of death)
- B. Decision to treat
 - Course of SACT agreed at MDT/ If PS 3/4 - patient discussed at MDT prior to palliative SACT commencing (17%, 4)
 - Grade of doctor initiating SACT/ prescribing this course of SACT (13%, 3)
 - Was SACT management appropriate? (17%, 4)
 - Was informed patient consent obtained? (17%, 4)

- Patient's performance status prior to most recent course of SACT (50%, 12)
- C. SACT prescriptions and administrations
 - Review of appropriate bloods (25%, 6)
 - Appropriate toxicity assessments (46%, 11)
 - Appropriate response assessments (21%, 5)
 - Pharmacy check of SACT prescription (8%, 2)
- D. Safety of SACT
 - Grade $\frac{3}{4}$ toxicity last cycle with appropriate modifications (dose reduction or GCSF) (13, 54%)
- E. End of life Care
 - Appropriate palliative care involvement (46%, 11)

Additional areas covered in the proformas included

- Cause of death (COD)/cause of death as documented on death certificate (100%, 24)
- Appropriate COD documented on certificate i.e no discrepancy with assessors opinion (13%, 3)
- Appropriate referral to coroner (29%, 7)
- An assessment of whether SACT contributed to death? (50%, 12)
- Recording of neutropenic sepsis deaths +/- an assessment of whether the NS was managed appropriately (34%, 8)
- Details of final hospital admission if applicable
(some specific questions re chemotherapy helpline contact/advice, delays in admission, consultant review, DNAR in place, ceiling of care documented)
- An assessment of whether care was acceptable or not.
- Deficits in care (71%, 24)
- Awareness of patient or relative complaints (8%, 2)
- Lessons to be learned (54%, 13)
- Areas of good practice (only 1 site specifically asked for this)

Conclusions following review of current practice:

- Need for any proforma to be user friendly and therefore consideration needs given to length, level of detail, time it will take to complete etc.
- Needs to be completed or have input from a senior physician, most likely the treating consultant, closely involved in the patients care.
- Value of senior independent review of **case notes** offering a second opinion particularly with regards SACT use, rather than simply the treating team's interpretation of the case.
- Need to avoid a simple tick box exercise and allow people to capture case context and complexity.
- Value of **focused questions** to encourage more critical review rather than simply summarising case details particularly with regards the appropriate and safe use of SACT.
- Potentially facilitates more individual reflection on practice and identification of personal learning needs.
- If the case is subsequently presented focuses and improves the quality of the discussion.
- Also improves standardisation of reviews/discussions and an assurance that all deaths are reviewed to the same high standard.
- Offers greater potential to identify system or process failures and facilitate quality improvement.
- Data collected more easily allows review/audit of guidelines.
- Value in also highlighting good practice and offering encouragement particularly to juniors who have been involved in often complex challenging cases.

Proposed Standardised Operational Policy and Review Template:

A standard operation policy (appendix 2) and comprehensive template to include the information collected on the locally developed proformas has been developed. The hope is that this will result in improved consistency, sharing of learning and the ability to pick up on themes that emerge in different

units to allow development of quality improvement plans. Each Trust can omit parts of the review template if they feel these are not key to their review process.

Appendix 1 –Trusts who provided information

Beaston West of Scotland Cancer Centre
Buckinghamshire Healthcare NHS Trust
Cambridge University Hospitals NHS Foundation Trust
Cancer Centre, Belfast Health & Social Care Trust (incorporates all cases within Northern Ireland)
Central Manchester University Hospitals NHS Foundation Trust
Colchester Hospital University NHS Foundation Trust
Edinburgh Cancer Centre, Western General Hospital
Guy's and St Thomas' NHS Foundation Trust
Kent Oncology Centre Maidstone Hospital
Lancashire teaching hospitals NHS trust
Norfolk & Norwich University Hospital NHS Trust
North Wales Cancer Treatment Centre
Nottingham University Hospitals NHS Trust, City Hospital Campus
Oxford University Hospitals NHS Foundation Trust.
Poole Hospital NHS Foundation Trust
Royal Derby Hospital Teaching Hospitals NHS Trust
Royal Free London NHS Foundation Trust
The Christie NHS Foundation Trust
Shrewsbury and Telford Hospital NHS Trust
Southend University Hospital NHS Foundation Trust
The Clatterbridge Cancer Centre NHS Foundation Trust
Tayside Cancer Centre, NHS Tayside
Torbay and South Devon NHS Healthcare Foundation Trust
University of Leicester NHS Trust
Velindre Cancer Centre
Weston Park Hospital Sheffield Teaching Hospital NHS Foundation Trust
Whittington Health, Magdala Ave London
Sheffield
North Midlands

Appendix 2: National Chemotherapy Board Sample 30 Day SACT Morbidity & Mortality Review Operational Policy

Background

The NCEPOD report “For Better, For Worse” audited deaths of 541 patients occurring within 30 days systemic anticancer therapy in 2008. This audit demonstrated good care in only 35% of cases, with room for improvement in 49% and less than adequate care in 8% of cases. In 27% of cases examined in the report, chemotherapy was felt to have caused or hastened death and 43% experienced grade 3 or 4 toxicity from their treatment. As a result of this the report made a number of key recommendations, one of which was that all deaths within 30 days of chemotherapy should be discussed in a Morbidity and Mortality or a clinical governance meeting.

The subsequent National Chemotherapy Advisory Group Report, “Ensuring Quality and Safety of Chemotherapy Services in England” has also made a number of recommendations regarding the safe delivery of a chemotherapy service and also has highlighted the need for each chemotherapy service to develop morbidity and mortality meetings to “review practice, policies and procedures in relation to the safety and quality of chemotherapy.”

Format of 30 Day SACT Morbidity & Mortality Meeting

The focus of the meeting is primarily educational and to improve patient care.

Insert detail of where and when the meetings are held and whether site-specific etc

Identification of patients

Patients will be identified by *state the methods used in your Trust* and a list sent to the 30 day M&M meeting co-coordinator. The list will be reviewed to identify patients who meet the inclusion criteria for review. The coordinator will email the relevant consultant asking them to complete sections 1-5 of the 30 Day SACT mortality proforma.

If the patient died in another hospital the treating oncologist should inform the local consultant for that admission that the patient will be discussed and invite them to attend the meeting.

It is viewed as good practice that where a patient dies within 30 days of SACT that the oncology notes should be held by the consultant. If the patient died in another hospital/at home the relevant notes/further information should be requested in anticipation of discussion at the 30 day SACT M&M meeting.

Criteria for Review

Inclusion Criteria

- Patients who received intravenous, oral or subcutaneous chemotherapy, monoclonal antibodies, targeted therapies or immunotherapy who died within 30 days of receiving SACT
- The 30 day period is defined as 30 days from the first day of the SACT cycle immediately prior to death. When SACT is given continuously, then the 30 day period is defined as death within 30 days of the last prescription

Exclusion Criteria

- Patients receiving hormone therapy alone
- Patients receiving bisphosphonates alone

Roles

Coordinator

Responsible for

- Maintaining list of cases for discussion and outcome
- Administration of the 30 day SACT mortality meeting
- Production of a prospective annual list of reviewers and Chair for each meeting
- Maintaining attendance list
- Producing minutes of meetings
- Compiling annual report for the Clinical Director to disseminate as appropriate (including attendance list)
- Ensuring completion of agreed actions

Chair

Responsible for

- Ensuring effective progress of meeting
- Facilitating discussion about the cases
- Agreeing minutes and actions with the coordinator

Treating Consultant

Responsible for

- Review of the case by completion of sections 1-5 of the 30 Day SACT mortality proforma and emailing to the meeting co-ordinator within 2-weeks.
- If overall standard of care assessed as B-E in section 5;
 - Making the relevant clinical notes available to the independent reviewer at least two weeks prior to the meeting
 - Focused presentation of the case summary at 30 day SACT M&M meeting

Reviewer (responsibility for all consultant oncologists to participate)

Responsible for

- Review of the case and answers provided in sections 1-5 and completion of section 6
- Highlighting areas of good practice, identify areas for improvement and raise appropriate questions for discussion by the rest of the meeting
- Completion and submission of the electronic review record to the meeting coordinator by 5pm on the Wednesday preceding the meeting
- Focused presentation of independent review at 30 day SACT M&M meeting
- Finding someone to swap their review month if unable to attend and letting coordinator know details of swap
- Each consultant will be responsible for reviewing approximately 6 cases per year

Clinical Governance

This section to be reviewed and updated with local procedures.

The meeting should give consideration to whether there should be retrospective discussion with the Coroner's Service in cases where this didn't happen at the time and where there has been felt to be deficiencies in care.

It is recognized that any learning needs to be timely to be effective. If a consultant is not able to obtain notes within 2 weeks to allow a case summary to be completed it is their responsibility to let the administration manager know so that notes can be sourced.

An annual Oncology 30 Day SACT M&M Meeting Report will be produced documenting patterns of care for all patients dying within 30 days of systemic therapy. This report will be held by the Clinical Director and disseminated as appropriate. Attendance by all medical staff is encouraged and attendance at a minimum of 6 meetings per year will be required for completion of satisfactory consultant appraisal/Specialty Trainee ARCP.

It is anticipated that all consultants should keep a record of their attendance, cases presented and reviewed in their appraisal folder and a reflective portfolio of learning points from personal cases for revalidation.

Appendix 3: Proposed 30 Day Systemic Anti-Cancer Therapy (SACT) Mortality Proforma.

Sections 1-5 to be completed by treating consultant

Section 1. Patient & Disease Details

Patient ID	Oncology Consultant	Form completed by
Patient Initials	Treating hospital/unit	Date completed
Age	Known to palliative care (Delete 2 choices)	
Gender M/F (Delete 1)	Yes No Unknown	
Primary Tumour <i>ie lung</i>	Treatment Intent (Delete 3 choices)	Co-morbidities (Delete 2 choices) YES NO Unknown
Histopathology <i>ie adenocarcinoma</i>	Neo-adjuvant Adjuvant	List:
Stage at Death: <i>ie TNM and stage</i>	Palliative-please state line Curative	Clinical Trial patient? YES NO (Delete 1)

Section 2. Assessment of SACT Use

Date of decision to treat	<i>Enter date/ not documented DD/MM/YY /Not doc</i>			SACT Regimen and Interval	<i>i.e Gem/carbo q3/52ly</i>	
Cycle (inc. number planned) Regimen listed in the site-specific algorithm	<i>Cycle X of Y YES NO (Delete 1)</i>			Did death occur within 30 days of final SACT cycle	<i>Please write how many days YES NO</i>	
Written informed patient consent obtained (Review consent form and documented toxicities) (Delete as required)	YES NO Consent-Good Average Poor			Grade of person consenting (Delete as required)	Consultant ST3+ Nurse Other-	
ECOG pre cycle 1 (at consent)	PS= <i>x/Not doc</i>			ECOG at final cycle	PS= <i>x/Not doc</i>	
Last SACT cycle prescribed by whom? (Delete 3 choices)	Consultant ST3+ Nurse Other-			SACT prescription signed by: (Delete as required)	Approved doctor Approved pharmacist Other	
Written protocol available for this regimen?	<i>(Delete 1 choice)</i> Yes No			Was there an appropriate response assessment to SACT documented (Delete 1)	YES NO Comment -	
Was there a deviation from protocol?	<i>(Delete 1 choice)</i> Yes No Comment-					
Was dose appropriate for: (state yes/no)	BSA/weight accounting for any dose reduction	FBC	Renal function	Hepatic function	Cardiac function	Other?
<i>Please give detail if answer no above</i>						
Where there any Grade 3/4 toxicities prior to final SACT cycle (Delete as required)	Not applicable (1 st cycle) None documented Yes -			In your opinion was the appropriate dose administered i.e. dose reduction if required		

In retrospect was the decision to treat with this regimen appropriate: (Delete 1) YES NO Comments -	In retrospect was the last SACT administration appropriate: (Delete 1) YES NO Comments -
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Section 3. Assessment of final hospital admission (if applicable) and cause of death

Date of death	DD/MM/YY	Place of Death (Delete 3 choices)	Hospital Home Hospice Other -
Emergency admission prior to death (Delete 1) YES NO	Date: DD/MM/YY Length of admission Days	Comment on communication with chemotherapy helpline/acute oncology/on-call onc/haem teams	
Cause of death as per your assessment		Cause of death as per death certificate	
Death likely related to recent SACT (Delete 3 choices)	Definitely Probably Possibly No Comment -	Death reported to coroner if SACT contributory to death (Delete 3 choices)	Yes No Unknown Not required
Neutropenic Sepsis (prior to death) (Delete 1) YES NO	Review neutropenic sepsis management Timely appropriate first line ABXs given?	VTE Venous Thromboembolism (prior to death) (Delete 1) YES NO On (Delete 1) -VTE prophylaxis -Therapeutic anticoagulation	Any concerns regarding management -

Section 4. Other information

Any other deficiencies in care noted/lessons to be learnt:

Section 5. Overall Standard of Care

Please tick	Description	Review process
A Good Practice <input type="checkbox"/>	A standard that you accept for yourself, your trainees and your institution	No further review required, written summary as part of M&M minutes only
B Room for improvement <input type="checkbox"/>	Aspects of clinical care that could have been better	Second in depth review to be conducted by Consultant who was not directly involved in care of the patient. Requires presentation at local M&M meeting and outcome/learning shared in minutes and through relevant Trust governance process.
C Room for improvement <input type="checkbox"/>	Aspects of organisational care that could have been better	
D Room for improvement <input type="checkbox"/>	Aspects of clinical and/or organisational care that could have been better	
E Less than satisfactory <input type="checkbox"/>	Several aspects of clinical and/or organisational care that were well below satisfactory	Please report a clinical adverse incident. Second in depth review to be conducted by Consultant who was not directly involved in care of the patient. Requires presentation at local M&M meeting and outcome/learning shared in minutes, through relevant Trust governance process and report to Medical Director & relevant manager.

Section 6. Independent Consultant Review

(To be completed by consultant reviewer if overall standard of care assessed as B-E in Section 5).

Form completed by:	Date completed
Are you in agreement with the answers provided in Sections 1-5. If not please list any discrepancies, any other deficiencies in care or learning issues.	
Highlight areas of good practice:	
Recommendations:	

Section 7. Mortality Meeting Review

Summary of discussion:		
In retrospect was the last SACT administration appropriate? <i>(Delete 1)</i> YES NO	Were complications managed appropriately? <i>(Delete 1)</i> YES NO	Did SACT cause or hasten patient's death? <i>(Delete 3)</i> Definitely Probably Possibly No
Recommendations and actions:		