Systemic Anti-Cancer Therapy Governance Framework

Guidance Notes

December 2018
Contents

Introduction .................................................................................................................................................. 2

Role of the regional cancer networks and the Managed Service Network for Children and Young People with Cancer .................................................................................................................. 3

Role of NHS boards .................................................................................................................................. 4

Role of Healthcare Improvement Scotland ................................................................................................. 4

External peer review process ....................................................................................................................... 5

Appendix 1 – External peer review process algorithm ............................................................................... 9

Appendix 2 – List of documentation required for board-level assessment .............................................. 10

Appendix 3 – Evidence of access/list of documentation required for site assessment ......................... 11

References.................................................................................................................................................. 13
Introduction

Background

Although ultimate responsibility for implementation of, and compliance with, national standards for Systemic Anti-Cancer Therapy (SACT) service delivery lies with individual NHS boards, Healthcare Improvement Scotland has developed a national governance framework to support consistency of care, share best practice and provide assurance. This guidance should be read in conjunction with the Systemic Anti-Cancer Therapy Governance Framework published in August 2018.

Purpose and scope

The purpose of this document is to provide additional guidance, in line with the Governance Framework, for NHS boards, regional cancer networks and the Managed Service Network for Children and Young People with Cancer (MSN CYPC). The aim is to help:

- stakeholders understand individual, local, regional and national roles and responsibilities
- support a standardised and consistent approach to assessment of SACT service delivery across Scotland, and
- avoid duplication of effort and resource in implementation of the framework.

It sets out guidance for external assessment teams and local NHS boards/sites preparing for peer review visits. The guidance notes should be used in conjunction with the accompanying audit tools.
Role of the regional cancer networks and the Managed Service Network for Children and Young People with Cancer

The regional cancer networks will co-ordinate the delivery of the external peer review programme within the specified 3-year time frame:

- to ensure all NHS boards in their region are scheduled for a board-level assessment and ahead of any individual site visits for that NHS board
- to ensure all sites delivering SACT services for adults within each NHS board is scheduled for assessment, and
- liaise with the MSN CYPC to identify assessors to participate in board level assessments where applicable.

The MSN CYPC will co-ordinate the programme for site assessment of services for children and young people.

The regional cancer networks/MSN CYPC will:

- Provide the NHS board/site to be assessed with an audit pack at least 3 months prior to the proposed month of the visit. The NHS board SACT Lead Clinician (or nominated lead) will then liaise directly with the external assessors to agree a mutually convenient date.
- Ensure that each individual peer review visit is subject to a clearly defined process within specified time frame.
- Ensure appropriate documentation is supplied to NHS boards and sites to complete the assessment process.
- Agree in advance with the NHS board SACT clinical lead the case mix and number of case records to be reviewed at each site. Cross-section to include appropriate range of cancer types/treatments and range of treatment delivery areas (day case, outpatients and inpatients as applicable).
- Co-ordinate onwards distribution of compliance reports to appropriate NHS board SACT Lead Clinician when received from the lead assessor.
- Liaise with the NHS board SACT Lead Clinician and Medical Director in the first instance, in the event of any issues of serious non-compliance being discovered.
- Receive exception reports from all NHS boards assessed and develop an action plan to address any common issues as necessary.
- Report on progress with the external peer review programme, in line with the SACT governance framework, to RCAG/MSN Board.
In the event of non-progression of serious non-compliance issues a report should be made to the NHS board Chief Executive, as appropriate. This will only occur after discussion with the NHS board SACT Lead and Medical Director.

If discussion with the NHS board Chief Executive does not resolve the serious non-compliance issues identified, then the regional/MSN SACT Group Chair will consider onward referral to HIS in line with the Systemic Anti-Cancer Therapy Governance Framework. This will only occur following discussion with the Chair of the Regional Cancer Advisory Group/MSN Board.

Role of NHS boards

NHS board and individual site self-assessment
- All NHS boards must complete NHS board and individual site self-assessments, prior to external peer review, using the published audit tools, and confirm to their regional cancer network that self-assessment has been completed.

External peer review
- NHS boards must work with their regional cancer network and the MSN CYPC to ensure that an external assessment of compliance is completed for each NHS board and individual sites within the agreed time frame.
- NHS board assessments should be undertaken prior to any site visits for that NHS board.
- NHS board and site assessments should not be undertaken on the same day.

Role of Healthcare Improvement Scotland

Healthcare Improvement Scotland will undertake a national external review after completion of the 3-year programme. A group of key stakeholders will be convened to:

- review a report from each of the regional cancer networks and MSN with an overview of progress and key findings, including good practice, from the intra-regional/MSN process
- review current NHS board-level exception reports and action/improvement plans
- identify areas where improvement support may be required
- make recommendations for further local, regional or national actions to help deliver improvements
- identify areas of good practice, and
- produce a report detailing the key findings from the external review, the recommendations of the group and areas of good practice.
External peer review process

The overall process is outlined in an algorithm in Appendix 1.

Local teams

The NHS board core team will include, as a minimum, the SACT Lead clinician, named pharmacist and named nurse.

The local team will consist of the appropriate leads involved in the prescribing, preparation and administration of SACT within the clinical area. For the purposes of arranging the external peer review specifics there should be a named core team at each site which will be visited. This is not limited to but must include a clinician, a nurse, a pharmacist and a service manager. There should be a nominated lead in each team who will act as the main local contact.

External peer review team

Peer review visits will be performed by and on behalf of the relevant cancer network/MSN by an external assessment team as defined in the SACT governance framework. Each team will comprise of a minimum of one clinician (either oncologist or haematologist), one nurse, one pharmacist. For larger sites more assessors may be required to ensure a reasonable cross-section of delivery areas and specialities can be covered. External assessors will have access to appropriate training, guidance and support throughout the process, there will be a lead assessor identified for each assessment team.

If issues or concerns arise within or about the external assessment team the point of contact will be the network manager who has co-ordinated the peer review visit in the site or NHS board.

Responsibilities of key personnel

Lead external assessor

- Will have attended a SACT governance training day in advance of visit.
- Acts as main point of contact for external team and required to attend in person.
- Leads the peer review process on the day of the visit (Appendix 1).
- Ensures a compliance report is delivered within the specified timescales.
- Escalates any serious non-compliance issues that are an immediate risk to patient safety immediately to the NHS board SACT Lead Clinician and the relevant regional SACT Group Chair.
- Sends a draft compliance report to the local team for factual accuracy check within 4 weeks.
- Submits final compliance report to Regional/MSN SACT group secretariat within 12 weeks of the visit date.
External peer review team

- Best practice is to have attended a SACT governance training day.
- Required to attend in person.
- Supports the lead assessor to deliver the external assessment visit.
- Supports completion the audit tool to produce a compliance report of the visit.
- Reviews drafts of the report within the specified timelines.

SACT Lead Clinician (or designate at a site)

- Arranges and agrees a date for the visit to suit all external and local team members.
- Liaises with site service managers to ensure appropriate documentation including access to electronically held guidelines and patient records are available to the external team on day of the visit.
- Prepares a timetable for the visit.
- Prepares for and participate in the review on the day of the visit.
- Facilitates the correction of non-compliance issues noted in the compliance report.
- Develops and agrees action plan and timescales to correct non-compliance issues with relevant staff.
- Reviews and responds to the draft compliance report within 2 weeks of receipt.
- Initiates immediate rectification of any serious non-compliance issues found and bring to the attention of the NHS board Medical Director.

Local team members

- Prepare for and participate in external assessment visit.
- Ensure availability of all documentation and evidence required (appendices 2 and 3).
- Review the draft compliance report for factual accuracy within 2 weeks of receipt.
- Support the SACT Lead Clinician in agreeing and progressing the action plan.

Visit schedule

The NHS board or site being assessed should be fully informed and prepared for the visit and ensure relevant personnel are available when required on the visit day. A timetable for the visit should be prepared in advance by the local team. It is envisaged that the compliance visit will take a day at most, perhaps part of a day for smaller services. The individuals who should be prepared to be present should include the following:

- service manager
- any other key managers or clinicians contributing to the service
- medical and, if applicable, non-medical prescriber representatives
- nursing professional either managing or delivering the service, and
• pharmacy staff managing SACT clinical pharmacy services and, when relevant, in the preparation and dispensing of SACT.

Adequate accommodation should be provided for the visiting team, a room will be required as the ‘base’ for the visit.

Relevant documentation should be readily accessible either as hard copies ready for review in the room or electronically. A list of documentation required is provided in appendices 2 and 3.

Arrangements should be made by the local team in advance to ensure the external team can view electronic documents and case records. An appropriate number and case mix of records, agreed in advance with the NHS board SACT Lead Clinician, must be available. Patient selected must have completed at least two cycles of treatment

At the end of the visit, the lead assessor will provide initial verbal feedback on findings to the SACT Lead Clinician and local team and agree timelines for reviewing and completing the final compliance report.

**Reporting**

The compliance report will be read by a range of senior staff whose knowledge of certain elements of CEL 30 (2012) may vary. Comments must therefore be detailed in full without ambiguity to inform action(s) required. The summary section and action plan must be written in terms which will be understood by someone with a non-clinical background. It is advisable to describe issues raised in terms of significance of risk to patients.

The external assessment team should:

• ensure current documentation is used for reporting
• complete the audit tool. Compliance should be recorded in the relevant column and a brief comment included where compliance is not fully achieved
• prepare a compliance report, and
• the completed compliance report should be forwarded to the Regional SACT group secretariat.

The Regional/MSN SACT group secretariat will then:

• send the completed compliance report to the SACT Lead Clinician for confirmation of accuracy and clarity.

The SACT Lead Clinician will then:

• share the compliance report with the local team and formulate an action plan, as required, to ensure compliance with the standards within the CEL
• send final compliance report and subsequent action plan to NHS board Medical Director and copy to: Local SACT Group, Director of Pharmacy, Nursing Director and Service Manager, Lead Pharmacist and Lead Nurse, and
• submit the action plan to the regional/MSN SACT Group for ongoing monitoring.

If any areas of significant concern or serious non-compliance are discovered, the lead assessor should highlight this to the SACT Lead Clinician during the de-briefing session. The SACT Lead Clinician should then immediately initiate rectification of any such issues. The lead assessor should also inform the regional/MSN SACT group Chair of any serious non-compliance issues without delay.

The secretariat will ensure that progress against local action plans is reviewed at regular intervals until all areas of non-compliance are rectified satisfactorily. This will allow for regional reporting on progress with compliance to the RCAG, a list of common regional issues will be compiled which can then be incorporated into the work plan for the regional/MSN SACT group.
Appendix 1 – External peer review process algorithm

Initial Actions by network/MSN:
- External assessors defined and recruited
- Audit tools and packs prepared and agreed
- Timelines determined
- Case mix for record reviews agreed
- Authoritative written support obtained from Regional Cancer Advisory Group (RCAG)/MSN Board

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<th>Months 1 - 3</th>
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<tr>
<td>7-week maximum process:</td>
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<tr>
<td>• 4 weeks to complete draft report</td>
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<tr>
<td>• 2 weeks for Board/site to comment on factual accuracy</td>
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<tr>
<td>• 1 week to finalise report</td>
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<td>4 weeks to address non-compliance issues</td>
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<tr>
<th>Months 3 - 5</th>
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<tr>
<td>Initial Compliance Report sent to:</td>
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<tr>
<td>SACT Lead Clinician</td>
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| M6 |
| Final Compliance Report sent to NHS board: |
| • Medical Director |
| • SACT Lead Clinician |
| • Service Manager |
| • Director of Nursing |
| • Director of Pharmacy |
| • Local Board SACT Group |

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<th>Key</th>
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<td>Cancer Network</td>
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<td>External Peer Review Team</td>
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<td>Local Team Members</td>
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<td>SACT Lead Clinician</td>
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Appendix 2 – List of documentation required for board-level assessment

Send to external team in advance of visit

- The previous SACT external assessment report and associated action plan.
- Current self-assessment compliance report.

Available for review on day of visit:

- Clinical Management Guidelines for all tumour types treated in the NHS board area.
- SACT Protocols for all tumour types treated in the NHS board area.
- Supportive treatment protocols. As a minimum:
  - neutropenic sepsis, in line with the Best Practice Statement for Management of Neutropenic Sepsis
  - nausea and vomiting
  - diarrhoea and constipation
  - mucositis
  - skin toxicity
  - tumour lysis syndrome
  - hypersensitivity reactions
  - management of immunotherapy related adverse events.
- Extravasation policy.
- Education and Training Programme.
- Standard SACT consent to treatment documentation.
- Intrathecal policy and register.
- List of non-medical prescribers.
- Morbidity and Mortality review policy and evidence of morbidity and mortality reviews.
- Quality, Risk, and Incident Management policies.
- Out of Hours SACT Policy.
- SOP for administration of SACT, including oral administration.
- SOP for labelling of oral SACT.
- Policies and SOPs for provision of SACT outwith centre/units if appropriate.
- Policies for accidental SACT spillage, disposal of SACT and disposal of patient waste.

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i Links to electronic copies of documentation which can be viewed by assessors are acceptable, hard copies are not required.
ii Not specified in CEL 30 (2012) but now considered to be good practice.
Appendix 3 – Evidence of access/list of documentation required for site assessment

Send to external team in advance of visit

- The previous SACT external assessment report and associated action plan.
- Current self-assessment compliance report.

Available for review on day of visit

- Clinical Management Plans where non-medical prescribing practised.
- Patient Case Records – pre-agreed mix of cases relevant to site and number proportionate to site size. The records will reflect the range of specialties and areas of service delivery – day case, inpatient and outpatient. The patient should have received at least two cycles of treatment.
- Corresponding SACT prescriptions.
- Training Records – Medical/Nursing/Pharmacist/Pharmacy Technician/ATO/Portering staff (if transporting SACT).
- Two intrathecal prescriptions (if relevant) – cross-checked with intrathecal register.
- Pharmacy:
  - external Aseptic Audit Report and corresponding action plan
  - SOP file
  - Pharmaceutical Care Plans
  - SOP for receipt and storage of SACT
  - SOP for dispensing of SACT
  - temperature logs, for example, to ensure appropriate storage of SACT agents.
- Clinical area SOP file.
- Example of an extravasation event.
- SOP for administration of SACT, including oral administration.

Evidence of access to and awareness of the following

- Clinical Management Guidelines for all tumour types treated in the clinical area.
- SACT protocols for all tumour types treated in the clinical area.
- Supportive treatment protocols. As a minimum:

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iii Links to electronic copies of documentation which can be viewed by assessors are acceptable, hard copies are not required.
- neutropenic sepsis, in line with the *Best Practice statement for Management of Neutropenic sepsis*
- nausea and vomiting
- diarrhoea and constipation
- mucositis
- skin toxicity
- tumour lysis syndrome
- hypersensitivity reactions
- management of immunotherapy related adverse events.

- Board-level policies and SOPs.
- Out-of-hours policy.
- Policies for accidental SACT spillage, disposal of SACT and disposal of patient waste.
References


