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Introduction

This document contains the updated national Governance Framework for Systemic Anti-Cancer Therapy Services. Additional guidance notes and associated audit tools developed by the multidisciplinary expert group will be available on Healthcare Improvement Scotland’s website by mid-October 2018.

Why do we need a Governance Framework for Systemic Anti-Cancer Therapy Services?

The treatment of cancer with medicines is commonly referred to as Systemic Anti-Cancer Therapy (SACT). Outcomes for patients following SACT are improving, but side effects are more common than with most medicines, and there is a higher risk of serious and potentially life-threatening complications.

There is a further risk in situations where part of the cancer treatment involves intrathecal administration (injection into the fluid around the spinal cord). At least 55 incidents are known to have occurred around the world (including the UK) where the anti-cancer medicine, vincristine, was given intrathecally instead of into the vein. This resulted in paralysis and, in almost all cases, was followed by death.

It is, therefore, important that systems are in place to support the provision of high quality care and ensure that the risk of complications is minimised as far as possible for all patients receiving SACT. This includes having specific measures in place to prevent the wrong medicine being given intrathecally.

These risks are recognised by the Scottish Government and it supports NHSScotland to maintain a high standard of care through two Chief Executive Letters:

- **Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy (SACT) CEL 30 (2012),** which:
  - promotes the safe delivery of SACT in all care settings, including patients’ own homes
  - provides guidance for safe practice in the prescribing, preparation, administration and disposal of SACT, and
  - requires NHS boards to be able to demonstrate compliance in discharging their clinical governance responsibilities by ensuring implementation and monitoring of the guidance.

- **Safe Administration of Intrathecal Cytotoxic Chemotherapy CEL 21 (2009),** which:
  - provides specific guidance for safe systems and practice, and
- requires the implementation of the guidance to be monitored by an NHS board designated lead reporting to the Chief Executive as part of their clinical governance procedures in compliance.

The guidance and standards in these CELs apply to the delivery of treatment for children, young people and adults in all care settings. These national standards provide NHS boards with a framework for safe delivery of SACT and NHS boards are required to demonstrate compliance with these.
Developing the Governance Framework for Systemic Anti-Cancer Therapy Services

SACT services are provided throughout Scotland. Each NHS board is responsible for delivery of these services in their sites. To support NHS boards to implement and monitor compliance with CEL 30 (2012) and CEL 21 (2009), Healthcare Improvement Scotland convened a multidisciplinary expert group to develop a governance framework and a national audit tool which was issued to NHS boards in March 2013.

The governance framework outlines the process that NHS boards must follow when undertaking mandatory audit of their SACT services for children, young people and adults. The three regional cancer networks, which are collaboratives involving all NHS boards in that region, have been tasked with supporting their constituent NHS boards in undertaking the required audits through self-assessment and intra-regional external peer review and overseeing the process. Each regional cancer network has a key steering group, known as the Regional Cancer Advisory Group (RCAG), or a Regional Cancer Advisory Forum in the case of the North of Scotland Cancer Network (NOSCAN), which is responsible for leading on this work. For children and young people under 25, services in Scotland are now co-ordinated by the Managed Service Network for Children and Young People with Cancer (MSN CYPC) which has its own governance structure and reports to the Cabinet Secretary.

National external review

Between 2013 and 2016, NHS boards completed self-assessments and the regional cancer networks co-ordinated peer reviews in line with the governance framework. In 2016, Healthcare Improvement Scotland convened a national external review group. The findings of this group and an overview of progress in NHSScotland, in relation to the implementation of national standards to support the safe delivery of SACT and compliance with the associated governance framework, was published in June 2017.

Refresh of the governance framework

Immediately following publication of national external review, Healthcare Improvement Scotland carried out a lessons learned survey of the current SACT governance framework. The survey identified that a refresh of the governance framework and audit tools was required. An expert group was convened, including representatives from the three cancer networks, MSN CYPC, public partners, Scottish Government and Healthcare Improvement Scotland (Appendix 1).
The Governance Framework for Systemic Anti-Cancer Therapy Services

The Governance Framework for Systemic Anti-Cancer Therapy Services is aligned to the governance framework in National Cancer Quality Programme CEL 6 (2012), which outlines the process NHS boards must follow when undertaking mandatory audit of SACT services. Figure 1 on page 9 shows each stage of the updated governance framework. Key stages are outlined below.

Key stages of the governance framework

Self-assessment
Self-assessment of SACT services must be undertaken by all NHS boards. These self-assessments should contribute to an NHS board level exception report for SACT services to address any areas of non-compliance and support preparation for intra-regional external peer review.

External peer review
NHS boards and all sites delivering SACT services within the NHS board area will be peer reviewed by teams of reviewers external to the NHS board. It is essential for the Board-level peer review that the team are all external to the NHS board and at least one reviewer must be external to the network. For site-level peer review, the team should be external to the NHS board and reasonable steps taken to include a team member from outwith the network.

The regional cancer networks will lead and arrange the external peer review process for NHS boards and sites delivering adult services. The MSN CYPC will lead and arrange the peer review process for sites delivering treatment for children and young people. This will involve identifying the schedule of peer review visits, ensuring all sites are visited at least every 3 years, and inviting external reviewers from other regions.

Involving public partners in the peer review process will be tested in selected sites.

The outcome and report from the peer review visit will inform Board-level and regional action/improvement plans. The judgement on whether the outcome is satisfactory or unsatisfactory rests with the lead auditor from the external review team. If there is potential cause for immediate concern, the lead auditor from the external review team must inform the NHS board involved, the appropriate RCAG or MSN Board and, if needed, escalate to Healthcare Improvement Scotland. Any issues raised will be subject to Healthcare Improvement Scotland’s escalation process.
All NHS boards and sites delivering SACT services within a cancer network should be audited as soon as practical, recognising that this will be dependent on the number of individual units within the region. The maximum completion time of a full round of audits is 3 years.

Following peer review, the findings must be internally reported and monitored through local NHS board clinical governance mechanisms. NHS board approved exception reports and action/improvement plans must be submitted to and monitored by the appropriate cancer network and, for children and young people’s services, to the MSN CYPC.

**National external review group**

Board-level exception reports and action/improvement plans must be submitted, via the cancer networks, to the expert review group. This group will be hosted by Healthcare Improvement Scotland. Membership will include medical, pharmacy, nursing and management representatives from each of the three cancer networks and the national MSN CYPC, Healthcare Improvement Scotland, and public partners.

The expert review group will meet every 3 years, produce a review of the exception reporting and submit it to the Scottish Cancer Taskforce.
1. **Development stage**

2. **Self-assessment**
   - NHS boards undertake self-assessment using audit tool within the first 6 months of the agreed timeframe.
   - NHS boards prepare board-level exception report and action/improvement plan to address any areas of non-compliance.

3. **External peer review**
   - NHS boards/sites are peer reviewed once every 3 years through intra-regional/MSN led process to inform Board-level and regional action/improvement plans.
   - Findings internally reported and monitored through local NHS board clinical governance mechanisms. NHS board approved exception reports and action/improvement plans submitted to RCAG/MSN.
   - Healthcare Improvement Scotland notified of any potential cause for concern, and issue subject to Healthcare Improvement Scotland escalation algorithm.

4. **National external review group**
   - The national external review group, hosted by Healthcare Improvement Scotland, reviews Board-level exception reports and action/improvement plans every 3 years.
   - Expert members will include medical, pharmacy, nursing and management representatives from each regional cancer network and MSN CYPC, Healthcare Improvement Scotland, public partners.
   - The national external review group will produce a report on the review of exception reporting for submission to the Scottish Cancer Taskforce.

5. **Improvement support**
   - Improvement approaches are considered.

6. **Monitoring**
   - RCAGs and MSN CYPC work with NHS boards to progress outstanding actions and monitor action/improvement plans.
   - Healthcare Improvement Scotland reports to Scottish Cancer Taskforce at annual external review.

7. **Escalation**
   - If progress is not acceptable, Healthcare Improvement Scotland will establish dialogue with the service concerned, visit if necessary and work with the NHS board and RCAG or MSN CYPC to address issues. The escalation process will be in line with current Healthcare Improvement Scotland’s escalation policy.
   - Report submitted to Scottish Cancer Taskforce through the Scottish Government Health and Social Care Directorates.
Status of this advice

The status of Healthcare Improvement Scotland advice and guidance is defined as one of the following three categories: 'mandatory', 'required to consider', or 'for information only'.

This governance framework has been endorsed by the Scottish Cancer Taskforce. Completion of audit of SACT services, in line with the governance framework and using the accompanying guidance notes and audit tools, is mandatory.

For more information about Healthcare Improvement Scotland, visit our website (www.healthcareimprovementscotland.org).
Approach to Systemic Anti-Cancer Therapy services delivery audits

In collaboration with the cancer networks and MSNs, Healthcare Improvement Scotland has developed additional guidance notes and updated audit tools. The aim is to support consistency of approach across NHSScotland in the assessment of compliance with Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy CEL 30 (2012) [Revised], Safe Administration of Intrathecal Cytotoxic Chemotherapy CEL 21 (2009) and Assessment, Diagnosis and Management of Neutropenic Sepsis Best Practice Statement.1, 3, 4

The guidance notes outline:

- roles and responsibilities at local, regional and national level
- suggested approach to intra-regional/MSN led peer review process
- examples of evidence requirements, and
- reporting arrangements.

The following audit tools are used for both self-assessment and peer review:

- Level 1 – Board-level assessment
- Level 2 – individual site assessment with patient record review

These guidance notes and audit tools will be available on our website from mid October 2018 (www.healthcareimprovementscotland.org).
# Appendix 1: Membership of the SACT working group

<table>
<thead>
<tr>
<th>Name</th>
<th>Surname</th>
<th>Role</th>
<th>Cancer Network</th>
<th>NHS board</th>
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<tbody>
<tr>
<td>John</td>
<td>Murphy</td>
<td>Consultant Haematologist</td>
<td>Chair</td>
<td>NHS Lanarkshire</td>
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<tr>
<td>Mark</td>
<td>Allardice</td>
<td>SCAN Modernisation Manager</td>
<td>SCAN</td>
<td>NHS Lothian</td>
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<tr>
<td>David</td>
<td>Cameron</td>
<td>Chair of Oncology and Co-director, Edinburgh Cancer Research Centre and Head of Cancer Services NHS Lothian</td>
<td>SCAN</td>
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<tr>
<td>Tracey</td>
<td>Cole</td>
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<tr>
<td>Tracy</td>
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Appendix 2: References


