

# NHS Scotland Systemic Anti-Cancer Therapy Services Review

A Report of Compliance against the CEL 30 SACT Governance Framework

2023

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# Report

## Introduction

Systemic Anti-Cancer Therapy (SACT) is the use of medicines to treat cancer. SACT often carries a higher risk of serious and potentially life-threatening complications compared with many other medicines. Therefore, it is essential to have systems in place to support the provision of high quality care and ensure that the risk of complications are minimised for all patients receiving SACT.

There is a further risk where part of the cancer treatment involves intrathecal administration of SACT (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, death.

The Scottish Government recognises these risks and it supports NHS Scotland to maintain a high standard of care through two Chief Executive Letters:

- [Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy \(SACT\) CEL30 \(2012\)\\*](#), 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 apply to the delivery of treatment for adults, children, and young people across all care settings, including independent health care.

## Governance Framework for Systemic Anti-Cancer Therapy Services

In 2018, in support of the implementation of CEL 30 (2012) and CEL 21 (2009), Healthcare Improvement Scotland (HIS), in collaboration with a multidisciplinary expert group reviewed, updated, and released the SACT governance framework and a national audit tool which detailed the standards that boards were required to meet in order to achieve CEL 30 and CEL 21 compliance.

The framework details the process for NHS boards to follow when undertaking mandatory audit of SACT services for adults, children, and young people. There are a number of key stages detailed within the governance framework including self-assessment, peer review, expert review group and improvement support. The governance framework and audit tool are available on the HIS website at: [SACT Governance Framework \(2018\)](#)

The three regional cancer networks (RCNs), in NHS Scotland include the West of Scotland Cancer (WoSCAN) Network, the South East Scotland Cancer Network (SCAN) and the North Cancer Alliance (NCA). The RCNs are collaboratives that include all NHS boards in that region, and are responsible for supporting their constituent NHS boards in undertaking the required audits and overseeing the process. Each RCN has a key steering group, which is responsible for leading on this work. In WoSCAN and SCAN this is known as the Regional Cancer Advisory Group (RCAG), in the case of the North Cancer Alliance (NCA), the NCA SACT Governance Group reports upwards via the NCA Operational Delivery Group.

For children and young people under 25, services in Scotland are co-ordinated by the Managed Service Network for Children and Young People with Cancer (MSNCYPC). This supports NHS boards in the delivery of cancer services to children and young people and has its own governance structure which reports to the Cabinet Secretary.

An overview of the boards and sites included within each RCN and the MSNCYPC in NHS Scotland is presented in appendix 1.

\*For noting, in June 2023 Scottish Government issued an update to the CEL 30 Guidance for the Safe Use of SACT. The contents of this report relate to the original version of the CEL30 Guidance, which was published in 2012, and the SACT Governance Framework, which aligns to this version.

## Impact of the COVID-19 Pandemic

This CEL30 (2012) audit cycle commenced in January 2019 and the original timeline had a deadline for completion of self-assessments and facilitated external review by January 2022, with delivery of a national external report of SACT delivery in NHS Scotland by autumn 2022.

Due to the COVID-19 pandemic, this audit cycle was put on hold in March 2020. The stage of completion that the audit cycle had reached pre-pandemic varied across Boards.

Because of pressures across the NHS in the period following the COVID-19 pandemic, the audit cycle did not resume until November 2022. Whilst it was acknowledged that SACT services continued to operate under pressure at this time it was recognised that there was a need to provide assurances that NHS Scotland's SACT services continued to provide safe clinical services for patients in line with the standards.

## Attenuated Approach

In view of the fact that SACT services were working under pressure and that the current CEL30 Guidance was under review, with an updated publication due from Scottish Government in 2023, HIS implemented an attenuated approach to providing the necessary assurance for this audit cycle. For boards and sites where an external audit had not been completed prior to the pause in the audit programme, the RCN / MSNCYPC were asked to review internal audit reports from the boards within their region, and complete validation of these by utilising peer auditors from within their own regional network. This replaced the external audit component of the governance. Refer to appendix 2 for full details of the attenuated approach requested to be undertaken.

In addition, the review of all returns and production of recommendations was undertaken by the internal HIS SACT Governance Leads in consultation with the Quality Assurance Directorate within HIS only. This avoided the formation of an expert review panel which would have required capacity from the regional teams during this time of high service pressure.

## Role of the RCN & MSNCYPC

In line with the SACT Governance Framework and SACT Governance Framework Guidance Notes published in 2018:

- The RCNs were responsible for liaising with boards within their network and coordinating the collation of the requested feedback for this audit cycle.
- The MSN CYPC were responsible for coordinating and collating the requested feedback for this audit cycle for children and young people SACT services.
- Both the RCNs and MSN CYPC were responsible for submitting the requested feedback to the HIS SACT Governance Team by the identified date, to ensure requested deadlines were met.

## Ongoing Pressures in SACT Services and Requested Modifications to the Attenuated Approach

In addition to post-pandemic recovery pressures being experienced, overall demand for SACT services has increased significantly in the past 9 years due to the rapid introduction of new SACT drug developments and approvals within NHS Scotland. As an illustration, centrally collected National SACT data has shown that between 2014 and 2021 NHS Scotland SACT services has seen an increase of 56% in patients treated with SACT, with an almost 70% increase in visits for SACT. Consequently, across Scotland, SACT services are currently experiencing significant capacity and workforce challenges to meet these demands, and the degree of dedication and commitment shown by teams within the Boards and Networks to undertake and report outcomes of the SACT Governance Board and Site audits is recognised and appreciated by the HIS Team.

Given the significant clinical pressure boards and regions were facing, a further adaptation to the internal validation process was requested for those WoSCAN sites which had not had an external audit carried out prior to the pause in the audit programme. This was because appropriate staff could not be released from the clinical setting to undertake the requested inter-regional peer review meetings. As an alternative, HIS requested that boards within WoSCAN provided assurances of the processes undertaken throughout the self-assessment process by completing a questionnaire to provide additional detail (see appendix 3). The WoSCAN RCAG, who are responsible for follow-up and reporting on action plans in the same manner as NCA and SCAN, validated these returns.

Following contact from the MSN CYPC, it became clear that additional training and time was required for completion of the requested information for all Children's and Young person's SACT Services. The HIS SACT Governance Team delivered a virtual training session, which was open to all sites and disciplines involved in the audits and agreed an extension of 3 months for return of the audit information.

# Summary of Returned Information and Recommendations

## Overview of good practice

There has been a consistent theme of dedicated teamwork and mutual support within SACT multidisciplinary teams across Scotland. Excellent compliance has been reported across Scotland with regards to CEL 21 the safe delivery of intrathecal SACT and the identification and management of extravasation.

In relation to education provision, SACT training and competencies appear well embedded within nursing with the use of the UKONS SACT passport and some areas are looking to strengthen this with clinical educator roles within adult SACT services. Pharmacy education and training plans were largely based upon a training plan produced by the Scottish Oncology Pharmacy Practice group (SOPPG), but it should be noted that the British Oncology Pharmacy Association (BOPA), have recently launched a national SACT verification training and competency framework passport that is intended to be used like the UKONS passport. There was significant input from Pharmacists working within NHS Scotland supporting this work, which should ensure it is applicable to Scottish practice. The allocation of dedicated learning time to complete training currently lies with individual boards.

Boards and RCNs reported strong governance structures in place to support and deliver SACT services, with some boards identifying areas where this requires some degree of strengthening, which reinforces the commitment to ensure the safe delivery of services. Examples of this include the update of SACT specific policies and restart of SACT specific governance groups that were paused during the pandemic.

Improvements and changes to how services, guidelines and documentation are stored and maintained with a move to more regional / national working and implementation of paperlite processes was evidenced. Some boards are continuing to review and work to improve regional access to essential IT platforms hosting guidelines and policies.

A significant amount of work to treat patients closer to home (for example using peripheral / outreach SACT units), where it is safe to do so, was evidenced, particularly across rural areas of Scotland. SACT service delivery to peripheral / outreach units can be a complex process, with SACT dispensed from a central aseptic dispensing unit (ADU) and delivered to the treatment sites. Some issues around logistical arrangements for timely access were reported, which require further review and improvement work.

## COVID-19 Pandemic Response Related Changes to SACT Services

Throughout the pandemic, many boards made rapid changes to SACT services to release capacity within hospitals and to ensure the continued safe and effective care of the vulnerable patient group receiving SACT. The majority of boards moved to remote SACT assessments, where it was safe to do so, via telephone reviews, near me consultations or other methods. For many services these changes have become business as usual, relieving some pressure on clinic space within outpatient departments, however it is imperative to note that outpatient appointments via virtual means continue to increase, so the associated workload has not reduced.

Some boards relocated SACT day units during the pandemic to reduce footfall within the main hospital buildings. Some of these arrangements have continued and have resulted in improved day case environments with potential for increased chair capacity. Again, it is important to note that the utilisation of increased chair capacity has not been fully realised in many areas due to both funding and recruitment / workforce constraints, however this does provide an opportunity for potential additional space should these constraints be resolved.

A number of boards moved to home delivery of oral SACT as another means to reduce footfall within the hospitals and remove the need for vulnerable patients to travel and attend the hospital environment. Boards developed appropriate SOPs to ensure that this was undertaken safely and consistently. Service and space efficiencies and good reception from patients led to some services moving to a business-as-usual model, however some were subsequently withdrawn due to lack of sustainable funding to embed them.

## [Review of Progress on Recommendations Made within SACT Delivery National External Review published in June 2017](#)

The HIS SACT Governance Leads reviewed the progress made by NHS boards on the recommendations made within the [SACT Delivery National External Review published in June 2017](#). The commitment of the SACT teams to undertake critical analysis, evaluation and service improvement for the majority of the recommendations was clearly demonstrated. The review confirmed that NHS Boards, RCNs and MSN CYPC have systems in place to support the safe delivery of SACT services.

Significant progress around the adoption of 'Once for Scotland' processes has been seen, although not all of these are yet fully embedded in practice. There is a clear national commitment to the development and implementation of the following documents and

processes to improve consistency and reduce duplication of effort within SACT Services across NHS Scotland:

- National implementation of the HIS SACT Consent Framework and use of standardised CRUK Consent forms has significantly improved compliance with SACT Consent processes across NHS Scotland. NHS Highland has implemented an e-consent process for SACT and are reviewing their SOPs to ensure a robust governance structure for this.
- The Scottish Cancer Network (SCN) was established in 2021 to take forward development of National Clinical Management Pathways (CMPs), with the aim of replacing Regional CMGs.
- A National SACT Protocol Template has been developed and approved for implementation across NHS Scotland SACT services. Guidance notes to support consistency in the development of SACT protocols accompany the template. The SACT Programme Board is now supporting further work to scope process and governance requirements for a potential once for Scotland process for SACT protocols.
- The National SACT data group has developed and implemented a national process for 30 Day SACT Morbidity and Mortality data to be collated and published from 2022 onwards.
- Development of a National SACT Non-Medical Prescribing framework is in progress and due for publication during 2023.
- Implementation of the UKONS SACT Passport for SACT nurse education, clinical competencies and annual revalidation of SACT competencies across all networks.
- National development of a Pharmacy SACT passport and SACT verification standards by the British Oncology Pharmacy Association (BOPA), which had significant input from Scottish Cancer Pharmacists.

There remain outstanding recommendations from the 2017 report, which are summarised in the table below:

<b>Standard 2: There are clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) in place, which are in line with CEL 30 (2012) and are readily available to all clinical staff involved in the delivery of SACT.</b>	
<b>Recommendation</b>	<b>2023 Progress Update</b>
2.4 NHS Dumfries Galloway to complete the implementation of its revised contingency plan.	March 2023 Site audit reports contingency plan being finalised.
2.6 Healthcare Improvement Scotland, via the ADTC Collaborative, to work with the Managed Service Network for Children and Young People with Cancer to streamline the process for local approval of SACT national guidelines.	Not yet achieved – refer to recommendation 1.8 later in this report.

2.7 The Managed Service Network for Children and Young People with Cancer to provide a progress update on the development of national supportive care guidelines and SACT protocols for all patients.	Not yet achieved – refer to recommendation 3.4 later in this report.
<b>Standard 5: SACT is prescribed, verified, prepared and administered correctly.</b>	
5.8 The Scottish Cancer Taskforce is asked to note that the expert review group strongly endorsed the objective of the Managed Service Network for Children and Young People with Cancer to progress a national approach to the implementation of electronic prescribing of SACT across NHS Scotland as a matter of urgency.	Not yet achieved – refer to recommendation E.2 later in this report.
<b>Standard 6: The patient is assessed for adverse effects at appropriate intervals using a recognised toxicity grading system, and adverse effects are being managed.</b>	
6.1 NHS Tayside to ensure haematology patients receiving oral SACT are assessed for adverse effects using a toxicity grading system.	Not yet achieved - Moving to ChemoCare V6 Upgrade during 2023 with plan to use electronic toxicity monitoring moving forward.
<b>Standard 7: All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed and learning shared.</b>	
7.2 Healthcare Improvement Scotland to facilitate a meeting with representation from SACT services to identify approaches for supporting national shared learning.	Not yet achieved – refer to recommendation 6.5 later in this report.
<b>Standard 11: All staff have the appropriate skills, knowledge and training.</b>	
11.1 All NHS board SACT lead clinicians should ensure that there are systems in place which provide specific reassurance that medical staff at trainee and staff grade level have the appropriate skills, knowledge and training required.	This has not been achieved consistently across all board areas. There is an opportunity for shared learning to ensure consistency of approach across Scotland.

The above recommendations are carried forward as appropriate into the recommendations for this audit cycle.

## 2019-2023 Audit Cycle

The recommendations in this report relate to the information submitted by the RCNs and MSN CYPC in March and June 2023 respectively. It is acknowledged that work will have been undertaken to address some of these prior to publication.

### Key messages / themes:

- Despite the reported current pressures in the system through increased demand for SACT and issues with recruitment, retention, and appropriate multidisciplinary staffing levels overall assurance of continued safe provision of NHS SACT services across NHS Scotland was demonstrated.
- It was noted that most services highlighted capacity and workforce issues across all disciplines and areas of service, and it is clear that these issues place a real risk on the future sustainability of safe SACT services across NHS Scotland. This should be addressed as a matter of urgency through the programmes of work being established such as the Oncology Transformation Programme, and targeted utilisation of SG funding provided for SACT services.
- There was a theme identified around the need for allocation of appropriate time within job-plans for SACT leads to fulfil responsibilities within both adult and CYPC services. It is also recommended that allocated time for both Pharmacy and Nursing SACT lead roles should be considered concurrently as per the recommendations within the revised CEL30 Guidelines.
- Several board and site areas identified that a number of guideline and policy documents were in need of review and update or required to be developed. In addressing these issues, some consideration could be made of how to reduce duplication of effort across SACT services and if Once for Scotland approaches are merited. For example, production and maintenance of SACT protocols, and supportive care guidelines, alongside the work SCN is progressing for Clinical Management Pathways.
- A lack of allocated time, and gaps in available support or resources for education and training activities were highlighted during the review by many services. Solutions to this should be explored, with consideration of development of National resources and / or support to reduce duplication of effort and ensure consistency of approach.
- Within some boards, it was identified that review of the approach to local review and sharing of learning from SACT related adverse events was required. More generally, there would be benefit in reviewing the regional and national approach to shared learning from adverse events, and HIS will undertake to look at the National approach aligned with wider national work on reviewing and learning from adverse events.
- It was noted that there were some gaps and inconsistencies reported in toxicity assessment recording. There would be a benefit in exploring a national approach to recording of toxicity assessments within an electronic system.
- Within the MSN CYPC some specific areas for action were identified:
  - There has been no reported progress in development of a National e-prescribing system for the MSN CYPC. Electronic prescribing is not fully implemented across

all CYPC services, with NHS Tayside being notable in continued use of paper prescribing, pending the implementation of a national system.

- There has been a lack of progress in recruitment of a Lead Pharmacy role within the MSN CYPC, which is pivotal to progression of above developments, alongside the ability to address unification of guidelines and protocols utilised in CYPC services. It is recommended the MSN progress this appointment as a matter of urgency.

Throughout the attenuated CEL30 audit process a number of SACT service constraints were highlighted by boards and although not directly related to the CEL30 audit process, they do have an impact on SACT service provision across NHS Scotland. These constraints include:

- A number of requests for mutual aid out with traditional health care boundaries were made throughout 2022-2023 to provide cover for oncology teams with lone tumour specific consultants or vacancies. Mutual aid was required to facilitate these boards to continue to provide local SACT Services for the affected tumour specific teams. Appropriate service level agreements or similar may be useful to formalise local / regional processes.
- Due to the rapid pace of new cancer medicines being reviewed / approved by SMC and NCMAG processes and the current workforce pressures, further consideration should be given to improvements in managing the introduction of new medicines. It is noted that the Chief Pharmaceutical Officer is taking forward work around this.

## Overview of Board Audit Outcomes and Recommendations

The CEL30 board audits encompass both Adult SACT Services, and Children and Young People’s SACT Services. Where outcomes, actions and/or recommendations are specific to only one of these service areas, this is highlighted for clarity in the following table. Refer to appendix 4 for an overview of the evidence required from NHS boards to demonstrate compliance.

<p><b>Section 1:</b> The NHS board has identified a Lead Clinician for SACT services (a consultant oncologist or haematologist) and documented their roles and responsibilities. They are supported by a senior pharmacist and a senior nurse (CEL 30 (2012) standards 1.1.3 – 1.1.7)</p>	
<p><b>Findings – Adult SACT Services</b></p>	<p>NCA – NHS Highland and NHS Western Isles identified that the job plan for the SACT Lead Clinician (who covers both boards) needs updated to ensure protected time is available to undertake the role.</p> <p>WoSCAN – NHS Greater Glasgow and Clyde (GGC) and NHS Lanarkshire identified that job plans for the SACT Lead Clinician need updated to ensure protected time is available to undertake the role.</p> <p>NHS Tayside and NHS Fife had not completed their annual SACT reports at time of review.</p>
<p><b>Recommendations</b></p>	<p>1.1 NCA to ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for the SACT Lead covering NHS Highland, and NHS Western Isles.</p> <p>1.2 WoSCAN to ensure appropriate job plans, with adequate time allocated to undertake the role, are in place for SACT Leads in NHS GGC and NHS Lanarkshire.</p> <p>1.3 NHS Tayside and NHS Fife SACT Leads to ensure production of annual SACT reports for review by appropriate board clinical governance group.</p> <p>1.4 All Boards - as recommended in the updated CEL30 (2023 revision) to ensure allocation of dedicated time for Pharmacy and Nursing SACT Leads, to undertake their responsibilities.</p>
<p><b>Findings – Children and young people’s SACT services</b></p>	<p>NHS Grampian and NHS Highland reported that job plans for the SACT Lead Clinician need revised to ensure protected allocated time is available for this role.</p> <p>NHS GGC has now formalised the role of the SACT Lead Clinician and clarified the reporting structure, however further work needs to be</p>

	<p>undertaken to recruit to this post and ensure dedicated time in the job plan to meet requirements.</p> <p>The MSN CYPC do not yet have a National Lead Pharmacist for the service in place.</p>
<b>Recommendations</b>	<p>1.5 NHS Grampian to ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for CYPC SACT Lead.</p> <p>1.6 NHS Highland to ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for CYPC SACT Lead.</p> <p>1.7 NHS GGC to progress recruitment of a SACT Lead Clinician with an appropriate job plan and adequate time allocated within their job plan to undertake the role.</p> <p>1.8 The MSN CYPC should progress recruitment to a National Lead Pharmacist role to support all boards across the MSN CYPC with progression of SACT related objectives including development of National CEPAS system business case, development of national supportive care guidelines, prescribing practices and SACT governance structures for CYPC services.</p> <p>1.9 All Boards - as recommended in the updated CEL30 (2023 revision) to ensure dedicated time is allocated for Pharmacy and Nursing SACT Leads, to undertake their responsibilities.</p>

<b>Section 2.</b> Capacity and workforce plans for SACT services are available and are reviewed and reported on a regular basis (CEL 30 (2012) standard 1.3.2)	
<b>Findings – Adult SACT Services &amp; Children and young people’s SACT services</b>	<p>All RCNs and MSN CYPC sites highlighted capacity and workforce as a concern for all disciplines including medical, pharmacy and nursing staff, with some boards reporting teams consistently working beyond safe capacity limits.</p> <p>Pharmacy services were specifically highlighted as being under-resourced in NHS Forth Valley, GGC, Borders, Dumfries, Grampian, and Highland.</p> <p>NHS Highland and NHS Western Isles indicated the requirement to update the annual report to local Clinical Governance Groups to ensure awareness of current challenges and risks, including capacity and workforce plans.</p>
<b>Recommendations</b>	<p>2.1 Key stakeholders to progress work to develop nationally consistent methodology to plan, review, monitor and report SACT</p>

	<p>capacity and workforce issues. It is requested that SACT programme Board consider taking forward a piece of work to address this recommendation, including consideration of a process to facilitate national oversight and escalation pathway for SACT capacity and workforce issues.</p> <p>2.2 Appropriate reporting structures should be utilised for reporting SACT workforce and capacity issues locally / regionally and escalation plans developed.</p> <p>2.3 NHS Highland and NHS Western Isles to develop annual reports that adequately reflect workforce and capacity overview and there is a clear pathway for escalation to appropriate board governance groups.</p>
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<p><b>Section 3:</b> There are clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) in place (CEL 30 (2012) standards 1.1.8, 1.4, 1.5, 7.1 and Best Practice statement for Assessment, Diagnosis and Management of Neutropenic Sepsis: SGHD Sep 2011)</p>	
<p><b>Findings – Adult SACT Services</b></p>	<p>NCA have made progress with production of Regional CMGs but do not yet have these fully in place due to limited capacity.</p> <p>NHS Grampian have made good progress with development and implementation of SACT protocols, however they have been unable to produce these for all regimens due to capacity limitations. They estimated that SACT protocols are in place for approximately 70% of regimens in use.</p> <p>NHS Lothian and NHS Ayrshire &amp; Arran reported their CEPAS Contingency processes required updating.</p>
<p><b>Recommendations</b></p>	<p>3.1 RCNs to encourage engagement of clinicians and pharmacists in development of National Clinical Management Pathways (CMPs) via the SCN work programme to reduce duplication of effort in development and maintenance of these.</p> <p>3.2 HIS and SCN to lead on work to scope out the implementation of a National SACT protocol process to reduce duplication of effort involved with production and maintenance of these.</p> <p>3.3 Given the risks associated with CEPAS / IT failure / downtime NHS Lothian and NHS Ayrshire &amp; Arran should ensure up to date contingency plans are available and accessible to all disciplines of staff.</p>

<p><b>Children and young people’s SACT services</b></p>	<p>NHS Grampian, Highland, Lothian and Tayside reported that a number of supportive care guidelines were out of date or in need of development. There was widespread support across the MSNCYPC for production of national guidelines.</p> <p><i>Refer to section A of site audit findings for full details on supportive care guidelines.</i></p>
<p><b>Recommendations</b></p>	<p>3.4 It would be mutually beneficial to formalise the governance processes for supportive care guidelines across the MSN CYPC utilising a phased approach to minimise duplication of effort and aim to develop a ‘Once for Scotland’ approach across the MSN CYPC. As identified in section 1 a lead pharmacist post-holder could be instrumental in co-ordinating and supporting this process.</p>

<p><b>Section 4.</b> The decision to initiate a new course of SACT is taken by a consultant oncologist / haematologist and the patient has provided written informed consent to receive SACT (CEL 30 (2012) standard 2.1)</p>	
<p><b>Findings – Adult SACT Services &amp; Children and young people’s SACT services</b></p>	<p>NHS Highland identified that their electronic SACT consent processes using FormStream do not currently align to the National regimen specific SACT consent process. Work is in progress to build regimen specific information into this system. Given the recent pause in the work exploring production of a business case for a national e-consent solution for NHS Scotland, NHS Highland acknowledge that their local governance structures to support their e-consent process need strengthened. In addition, NHS Highland noted that patients with incapacity are not currently able to sign e-consent forms.</p> <p>NHS Tayside identified the need to review their SOP for written consent to ensure clarity of process for staff involved.</p> <p>NHS Grampian identified the need to review consent processes to ensure that these work consistently and effectively for (all) remote sites.</p> <p>NHS Western Isles similarly identified that consent processes, undertaken within NHS Highland, required review to ensure consistency in SACT consent forms being available prior to first treatment.</p> <p><i>Refer to section C of site audit for findings related to the accessibility and completion of SACT Consent Forms.</i></p>

<b>Recommendations</b>	<p>4.1 NHS Highland to ensure their SACT Consent governance and process aligns with the HIS SACT Consent Framework and includes alternative processes for adults with incapacity to ensure consent is in place prior to treatment.</p> <p>4.2 NHS Tayside to revise their process for written consent to ensure there is clarity of process and responsibility across all staff groups involved in the process.</p> <p>4.3 NHS Grampian, NHS Tayside, NHS Highland, and NHS Western Isles to ensure appropriate processes are in place to enable access to SACT Consent forms either on paper or EPR (electronic patient record). These processes should be reviewed, monitored and action plans developed where required.</p> <p><i>Refer to section C of site audit outcomes for recommendations related to the accessibility and completion of SACT Consent Forms</i></p>
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<b>Section 5.</b> SACT is prescribed, verified, prepared and administered correctly (CEL 30 (2102) standards 3, 4.2.5-6, & 5)	
<b>Findings – Adult SACT Services &amp; Children and young people’s SACT services</b>	<p>NHS Tayside – there is a need to review medical and non-medical prescribing policy as recommended by <a href="#">Royal College of Physicians (RCP) external review</a></p> <p>NHS Borders - some SACT administration policies are out of date and require updating or uploading to local intranet page. Need to review medical and non-medical prescribing policy.</p> <p>NHS Orkney &amp; Shetland - local SOPs for SACT dispensing require review and update.</p>
<b>Recommendations</b>	<p>5.1 NHS Tayside to update their prescribing policy for medical and non-medical prescribing.</p> <p>5.2 NHS Borders to review and update SACT administration policies, and medical / NMP prescribing policies.</p> <p>5.3 NHS Orkney &amp; Shetland to review and update SOP for SACT dispensing.</p>

<b>Section 6.</b> All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed, and learning shared (CEL 30 (2012) standard 1.3.3)	
<b>Findings – Adult SACT Services &amp;</b>	NHS Fife reported that clinical incident review meetings were stopped during the COVID pandemic but planned to restart these in

<p><b>Children and young people's SACT services</b></p>	<p>Q1 2023 &amp; incident review meeting minutes will be shared with board clinical governance committee.</p> <p>NHS Forth Valley identified that they need to embed the SACT Governance Group and clinical incident reporting into new Forth Valley Governance Structures and plan to create a learning bulletin.</p> <p>NHS Tayside acknowledged the need to identify and implement ways of improving sharing of learning from meetings/LAERs.</p>
<p><b>Recommendations</b></p>	<p>6.1 NHS Fife to confirm re-establishment of SACT incident review meetings and to ensure appropriate communication of shared learning locally and regionally.</p> <p>6.2 NHS Forth Valley to provide an update to assure that clinical incident reporting has been embedded into new Forth Valley Governance Structures.</p> <p>6.3 NHS Tayside to provide an update to assure that they have implemented processes to improve sharing of learning from local adverse event reviews.</p> <p>6.4 RCNs should facilitate regular meetings with representation from their constituent boards to identify regional shared learning opportunities.</p> <p>6.5 HIS to develop a suitable process for national shared learning opportunities from SACT related incidents with regional stakeholders.</p> <p>6.6 The MSN CYPC should facilitate regular meetings with representation from all boards to identify national shared learning opportunities.</p>

<p><b>Section 7.</b> Administration of intravenous SACT includes techniques to minimise risk of extravasation and procedures for management of the suspected or actual extravasation (CEL 30 (2012) standard 6)</p>	
<p><b>Findings – Adult SACT Services</b></p>	<p>RCNs report full compliance in all aspects of standard 7.</p>
<p><b>Recommendations</b></p>	<p>Not applicable.</p>
<p><b>Findings - Children and young people's SACT services</b></p>	<p>NHS Tayside and NHS Lothian identified that their local extravasation policies require review, update, and approval.</p>

<b>Recommendations</b>	7.1 NHS Tayside and NHS Lothian to ensure their extravasation guidelines are reviewed, updated, approved and easily accessible to clinical staff.
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<b>Section 8. Intrathecal cytotoxic chemotherapy is administered safely (CEL 21 (2009))</b>	
<b>Findings – Adult SACT Services</b>	<p>The external review team for the NHS Grampian Board audit highlighted that a pre-specified room for intrathecal SACT is not utilised and given the current COVID-19 pandemic the patient’s own room (in-patient) will continue to be used to reduce patient movement during the pandemic. Review of room utilisation in the outpatient area will be undertaken in the future.</p> <p>NHS Lothian acknowledged their intrathecal Policy requires review and update.</p> <p>All RCNs reports full compliance with the other aspects of standard 8.</p>
<b>Recommendations</b>	<p>8.1 NHS Lothian should ensure that intrathecal policies are up to date and comply with CEL 21 (2009).</p> <p>8.2 NHS Grampian should review existing mitigations for intrathecal SACT developed due to the COVID-19 pandemic when board level COVID 19 risk assessments deem this appropriate, to ensure full CEL 21 (2009) compliance.</p>
<b>Findings - Children and young people’s SACT services</b>	All boards across the MSN CYPC report full compliance with section 8.
<b>Recommendations</b>	Not applicable.

<b>Section 9. Death within 30 days is reported and reviewed (CEL 30 (2012 standard 1.3.4))</b>	
<b>Findings – Adult SACT Services &amp; Children and young people’s SACT services</b>	<p>NHS Borders identified the need to arrange Lead Team access to haematology Morbidity and Mortality (M&amp;M) reports for deaths occurring within 30 days of administration of SACT.</p> <p>NHS Fife Haematology team identified the need to resume 30 Day M&amp;M meetings and document outcomes.</p>
<b>Recommendations</b>	9.1 NHS Borders to ensure robust arrangements are in place for 30 day M&M reviews for haematology patients and ensure that all

	<p>appropriate personnel and governance groups have access to these at a local and regional level where applicable.</p> <p>9.2 NHS Fife to ensure robust arrangements are in place for 30 day M&amp;M reviews for oncology and haematology patients and ensure that all appropriate personnel and governance groups have access to these at a local and regional level where applicable.</p>
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**Section 10.** All staff have the appropriate skills, knowledge and training (CEL 30 (2012 standard 1.2.)

<p><b>Findings – Adult SACT Services &amp; Children and young people’s SACT services</b></p>	<p>NHS Grampian &amp; NHS Highland highlighted that due to workforce pressures, staff who require training had no protected time allocated. There is awareness of difficulties in delivering training, but ongoing service pressures are affecting the ability to reach a resolution. Work is underway to share TURAS training modules, develop an SOP for training new SACT nurses and develop a nurse educator role.</p> <p>NHS Tayside identified a gap in recording of training and stated an aim to establish training logs for all staff groups by July 23.</p> <p>NHS Ayrshire &amp; Arran identified that although medical staff undertake PDRs, there is not a formalised process for SACT prescribing reviews for Specialty doctor by oncologists for each tumour site.</p>
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<p><b>Recommendations</b></p>	<p>10.1 NHS Grampian and NHS Highland to make all efforts to recruit sufficient staff to alleviate workforce pressures and enable allocation of protected learning time for staff undertaking SACT training and SACT competencies.</p> <p>10.2 NHS Tayside to confirm establishment of training processes and logs for all disciplines of staff.</p> <p>10.3 NHS Ayrshire and Arran to develop a process for specialty Dr training and competency assessment.</p> <p>10.4 It would be beneficial to develop a nationally consistent template for documenting education provision and competency assessment for medical staff at specialty grade level and consultants who have trained outside of UK, to provide assurance that this group of staff have the appropriate skills, knowledge and training required to treat patients with SACT. The SACT Programme Board is asked to consider taking this forward. It is noted that the UK SACT Board is due to publish guidance on ‘Prescriber Competencies for</p>
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	Reviewing and Prescribing Systemic Anti-Cancer Therapy' in Q4 2023, which may be helpful to refer to.
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<b>Section 11.</b> Appropriate governance arrangements are in place for delivery of SACT outwith Cancer Centres/Units (CEL 30 (2012) standard 8)	
<b>Findings – Adult SACT Services &amp; Children and young people’s SACT service</b>	<p>NHS Tayside’s SOP for SACT delivery out with cancer centre required final approval.</p> <p>RCNs and all boards across the MSN CYPC report either full compliance with all other aspects of Standard 11 or do not deliver SACT out with a Cancer Centre / Unit.</p>
<b>Recommendations</b>	11.1 NHS Tayside should provide assurance that their SOP for SACT delivery out with the cancer centre has formal approval.

## Overview of Site Audit Outcomes and Recommendations

Any recommendations identified in the board audit section will not be repeated in the site audit recommendations.

<b>Section A. Clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) are readily available to all clinical staff involved in the delivery of SACT (CEL 30 (2012) standards 1.4,1.5 &amp; 7.1)</b>	
<b>Findings – Adult SACT Services</b>	<p>NHS Grampian: Aberdeen Royal Infirmary highlighted the requirement to review the induction provided to junior medical staff and nurses to signpost them to key SACT supportive care resources.</p> <p>NHS Tayside have commissioned an intranet site to improve the accessibility of key policies and SOPs for all NHS Tayside users.</p> <p>NHS Highland are seeking support for the development of a reliable IT infrastructure between boards to support remote working.</p>
<b>Recommendations</b>	<p>A.1 NHS Grampian and NHS Tayside to ensure key SACT supportive care resources are easily accessible to all members of the multidisciplinary team across the organisation.</p> <p>A.2 NHS Highland to seek support of NCA and other stakeholders to progress reliable IT Infrastructure which supports remote / cross-boundary working.</p> <p>Refer to section 3 of the board audit for related recommendations.</p>
<b>Findings – Children and young people’s SACT services</b>	<p>A number of NHS Boards acknowledged that supportive care guidelines were overdue review.</p> <p>NHS Tayside (Children’s Hospital Dundee):</p> <ul style="list-style-type: none"> <li>• Tumour lysis</li> <li>• Anti-emetic</li> <li>• Skin toxicity</li> <li>• Hypersensitivity.</li> </ul> <p>NHS Grampian (Aberdeen Children’s Hospital):</p> <ul style="list-style-type: none"> <li>• Paediatric amendment to be added to the immunotherapy guideline.</li> </ul> <p>NHS Highland (Children’s Unit Raigmore Hospital, Inverness):</p> <ul style="list-style-type: none"> <li>• Mucositis</li> <li>• Nausea &amp; vomiting</li> <li>• Diarrhoea &amp; Constipation</li> <li>• Skin Toxicity</li> </ul>

	<ul style="list-style-type: none"> <li>• Tumour Lysis</li> <li>• Hypersensitivity.</li> </ul> <p>NHS Lothian (Royal Hospital for Children and Young People, Edinburgh):</p> <ul style="list-style-type: none"> <li>• Constipation</li> <li>• Mucositis</li> <li>• Skin Toxicity</li> <li>• Hypersensitivity</li> <li>• Immunotherapy Adverse Events.</li> </ul> <p>At present there does not seem to be consistency in the responsibility for the development, review, and approval processes for supportive care guidelines across the MSN CYPC, with some guidelines developed by boards and others by regions or nationally via the MSN CYPC. This is likely to cause duplication of effort and potentially variation in practice.</p>
<b>Recommendations</b>	<p>A.3 To ensure shared learning from the site audits from Adults Services, consideration should be given to where guidelines are hosted to ensure they are easily accessible to all members of the multidisciplinary team across the MSN CYPC.</p> <p>Refer to recommendation 3.4 in board audit section for further related recommendation.</p>

<b>Section B. The decision to initiate a new course of SACT is taken by a consultant oncologist / haematologist (CEL 30 (2012) standard 2.1.5)</b>	
<b>Findings – Adult SACT Services</b>	<p>Borders General Hospital within NHS Borders identified:</p> <ul style="list-style-type: none"> <li>• Issues with timely access to MDT reviews</li> <li>• Communication of treatment plans with GPs</li> <li>• Accessibility of dermatology MDT outcomes in remote cancer units</li> <li>• Issues with accessibility of SACT dose and treatment amendments / decisions.</li> </ul>
<b>Recommendations</b>	<p>B.1 NHS Borders to ensure processes are in place facilitate clear, unambiguous, and timely access to MDT reviews, management plans and advising GP of the treatment plan for all first presentations of cancer across all tumour groups.</p> <p>B.2 NHS Borders to ensure that there are mechanisms in place to improve access to documentation of changes to SACT prescriptions and treatment decisions.</p>

<b>Findings – Children and young people’s SACT services</b>	Aberdeen Children’s Hospital within NHS Grampian identified issues relating to the documentation of the decision to initiate a new course of SACT by an oncologist / haematologist. In one case the MDT review was not documented and in another it was available on the GGC sci store, however not the local one.
<b>Recommendations</b>	B.3 NHS Grampian to ensure a process is developed to consistently ensure MDT discussion is documented and available within the required timeframe.

<b>Section C. The patient has provided written informed consent to receive SACT (CEL 30 (2012) standards 2.1.4 &amp;2.2.1)</b>	
<b>Findings – Adult SACT Services</b>	<p>A few themes were identified with regards to the consistency of the consent process namely:</p> <ul style="list-style-type: none"> <li>• Ensuring the use of the correct SACT Specific Consent Form (NHS GGC - Vale of Leven)</li> <li>• Consent form being fully completed (NHS Fife -Queen Margaret Hospital &amp; Victoria Hospital)</li> <li>• Borders General Hospital &amp; Aberdeen Royal Infirmary have moved to paperlite processes where consent forms should be uploaded onto local IT systems and there have been issues with the consistency of this being undertaken in a timely manner.</li> </ul> <p>NHS Tayside &amp; NHS Western Isles identified that the local SOPs to support the national consent process required updating.</p>
<b>Recommendations</b>	<p>C.1 NHS Tayside to update local SACT Consent SOPs to support the national SACT consent process.</p> <p>C2. NHS Highland SACT team to work with NHS Western Isles teams and review consent processes to ensure consistent availability of signed consent prior to commencing SACT.</p> <p><i>Refer to section 4 of the board audit for related recommendation.</i></p>
<b>Findings – Children and young people’s SACT services</b>	All sites across the MSN CYPC report full compliance with section C.
<b>Recommendations</b>	<i>Refer to section 4 of the board audit for related recommendation.</i>

<b>Section D. The performance status of the patient is documented (CEL 30 (2012) standards 2.1.6 &amp; 3.1.6)</b>	
<b>Findings – Adult SACT Services</b>	RCNs report full compliance with all aspects of Section D.
<b>Recommendations</b>	Not applicable.
<b>Findings – Children and young people’s SACT service</b>	Children’s Hospital Dundee within NHS Tayside do not currently use an electronic prescribing system to prescribe SACT. They do however report that prior to each new cycle of SACT, performance status is documented on the paper clerking form, using the CTCAE grading system.
<b>Recommendations</b>	Refer to recommendation E.2 below.

<b>Section E. SACT is prescribed correctly (CEL 30 (2012) standard 3)</b>	
<b>Findings – Adult SACT Services</b>	NHS Tayside identified the need to review medical and non-medical prescribing policies, however it is noted that a national SACT NMP framework is currently under development, which may influence timescales for the NMP framework.
<b>Recommendations</b>	Refer to recommendation 5.1
<b>Findings – Children and young people’s SACT service</b>	Children’s Hospital Dundee within NHS Tayside do not currently use an electronic prescribing system for SACT.
<b>Recommendations</b>	E.2 MSN CYPC must provide an update on progress with the national approach to electronic prescribing implementation. In the 2017 National external review it was recommended: ‘5.8 The Scottish Cancer Taskforce is asked to note that the expert review group strongly endorsed the objective of the Managed Service Network for Children and Young People with Cancer to progress a national approach to the implementation of electronic prescribing of SACT across NHS Scotland as a matter of urgency’. This is particularly impacting on the service in Children’s Hospital Dundee, where a paper-based system continues to be used.

<b>Section F. SACT is verified correctly (CEL 30 (2012) standard 4.1)</b>	
<b>Findings – Adult SACT Services</b>	The NHS GGC, Beatson West of Scotland Cancer Centre (WoSCC) external CEL30 site audit carried out prior to the pandemic observed some issues with SACT verification. Some reprints of SACT prescriptions were missing signatures. The local team identified that there had been an increase in reporting of incidents relating to verification. Issues related to the clinical area in which pharmacists

	<p>work, with distractions, staffing gaps and workload were listed as significant contributing factors. An improvement plan was developed however was put on hold during the COVID pandemic. National Capacity work was subsequently completed showing a significant gap in pharmacy resource vs workload.</p> <p>NHS Grampian: Aberdeen Royal Infirmary (ARI) identified that within an oral SACT clinic there was non-compliance with the SACT verification standard (4.1.1), with only cycle 1 SACT prescriptions being verified due to lack of pharmacy capacity.</p>
<b>Recommendations</b>	<p>F.1 Beatson WoSCC to provide a progress report on compliance to the SACT verification standards (section 4.1) within CEL30 (2012).</p> <p>F.2 ARI in NHS Grampian to ensure compliance with pharmacist verification standards for all prescribed cycles of SACT in ARI, and to provide HIS with evidence of action plan and progress against this action.</p>
<b>Findings – Children and young people’s SACT service</b>	All sites within the MSN CYPC report full compliance with section F.
<b>Recommendations</b>	Not applicable.

<b>Section G. SACT prepared and dispensed correctly (CEL 30 (2012) standards 4.2.1-4, 4.3 &amp; 4.4)</b>	
<b>Findings – Adult SACT Services</b>	NHS Orkney and NHS Tayside identified that SACT dispensing policies required review and update.
<b>Recommendations</b>	G.1 NHS Orkney and NHS Tayside to confirm that SACT dispensing policies have been reviewed, updated, and approved.
<b>Findings – Children and young people’s SACT service</b>	<p>Ninewells Hospital within NHS Tayside reported full compliance with Section G but noted that their aseptic audit was incomplete due to pharmacy workforce pressures.</p> <p>Aberdeen Children’s Hospital within NHS Grampian identified a minor non-compliance with recording of delivery of oral SACT to the ward due to pharmacy workforce pressures, however, have reported systems will be in place by August 2023 to address this.</p> <p>The Children’s Unit Raigmore Hospital, Inverness within NHS Highland report that the system for the verification and release of SACT has not yet been formalised. It was reported that plans are in</p>

	place to ensure a SOP is developed for the verification and release of SACT by October 2023.
<b>Recommendations</b>	<p>G.2 NHS Grampian to confirm systems are in place to record delivery of oral SACT.</p> <p>G.3 NHS Highland to confirm implementation of SOPs for SACT verification and release.</p>

**Section H. Areas used for SACT administration are safe and appropriate (CEL standard 5.1.2, 5.1.4, 6.2.2, 9.4.2)**

<b>Findings – Adult SACT Services</b>	<p>The risk assessment tool for areas administering SACT was utilised to risk assess clinical SACT administration areas across NHS Scotland with the exception of NHS Fife and Saint John’s Hospital (SJH) within NHS Lothian.</p> <p>Throughout the pandemic, a number of SACT units required to move for a variety of reason including to increase in-patient bed availability and to reduce risk for high-risk cancer patients. The RA Tool was useful to assess potential new temporary SACT day units throughout the pandemic, with some of these becoming permanent relocations post pandemic.</p> <p>Due to these quicker than normal moves in day unit locations a number of issues were identified via the RA Tool for example:</p> <ul style="list-style-type: none"> <li>• Lack of designated SACT Cupboard or SACT fridge storage</li> <li>• Secure rooms for SACT / supportive treatments to be stored</li> <li>• Issues with fridge temperature monitoring due to changes in equipment (particularly on days where day units were closed e.g. weekends)</li> <li>• Lack of barrier / isolation rooms (within RA but not specified directly within CEL30 (2012))</li> <li>• Not enough hand wash facilities</li> <li>• Not enough work surface area</li> <li>• Not enough space to deal with an unwell patient.</li> </ul> <p>Within NHS GGC Beatson WoSCC it was also identified that although there was lots of space, the area was busy and the overflow ward fridges not temperature controlled.</p> <p>Issues were also identified within Edinburgh Cancer Centre (ECC), Western General Hospital (WGH) NHS Lothian where the environmental assessment identified a feasibility study was required to assess for upgrade work when the haematology move was completed at the end of 2020. An update on this would be</p>
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	useful to see if this was able to be progressed throughout the pandemic.
<b>Recommendations</b>	<p>H.1 Queen Margaret Hospital and Victoria Hospital within NHS Fife and St John’s Hospital within NHS Lothian to undertake a risk assessment of areas that administer SACT and report back to HIS.</p> <p>H.2 All RCNs should review existing action plans from the completed risk assessments to ensure all appropriate actions have been addressed.</p> <p>H.3 HIS should undertake a review of the Risk Assessment Tool used for Areas Administering SACT.</p> <p>H.4 All boards and sites should ensure a self-assessment using the risk assessment tool is undertaken annually for all areas administering SACT and report into regional SACT groups.</p>
<b>Findings – Children and young people’s SACT service</b>	Children’s Hospital Dundee within NHS Tayside and the Highland Children’s Unit in NHS Highland do not have a fridge dedicated for SACT only, both areas have mitigated against this by having identified a specific drawer within the fridge dedicated for SACT. NHS Tayside had stated that they do not have the space for a separate SACT Fridge.
<b>Recommendations</b>	<p>H.6 All sites should ensure annual risk assessment undertaken for all areas administering SACT.</p> <p>H.7 It would be good practice to undertake a risk assessment for areas administering SACT when designing new day case or in-patient areas administering SACT or moving these services to another area.</p>

<b>Section I. Safe administration of SACT (CEL standards 5.1.3, 5.1.5, 5.1.6, 5.2)</b>	
<b>Findings – Adult SACT Services</b>	<p>The NHS Tayside SOP for the delivery of SACT outwith cancer centre needs final sign off via the appropriate governance route.</p> <p>Although there have been reports of improvements in SACT administration checks including: undertaking independent two nurse checks; ensuring 2 signatures; documentation of batch numbers; expiry dates and administration times for both SACT and supportive medications, a number of areas continue to report issues with inconsistent compliance with this when reviewing clinical notes (Borders General Hospital, Inverclyde Royal Infirmary and Vale of Leven).</p>

<p><b>Recommendations</b></p>	<p>I.1 NHS Tayside to confirm that their SOP for SACT delivery out with the cancer centre is approved via appropriate governance group.</p> <p>I.2 All boards should undertake regular auditing and monitoring of the following aspects of safe administration within their SACT Governance Groups to ensure compliance with CEL30 (2012):</p> <ul style="list-style-type: none"> <li>• 2 nurse independent checks</li> <li>• documentation of batch numbers</li> <li>• documentation of expiry dates and</li> <li>• documentation of administration times for both SACT and supportive medications.</li> </ul>
<p><b>Findings – Children and young people’s SACT service</b></p>	<p>NHS Tayside have highlighted that batch numbers for SACT are recorded in pharmacy, but not transcribed onto the patient labelled drug, therefore this cannot be documented on administration chart/prescription.</p> <p>Similarly, NHS GGC report that batch numbers are not included on any aseptically prepared SACT and are therefore not recorded in the administration documents. There needs to be some clarification if the batch numbers are stored within pharmacy to ensure there is some form of audit trail of SACT drugs / doses.</p> <p>NHS Lothian have acknowledged inconsistencies in the nursing documentation of date/time/batch and expiry on SACT prescriptions.</p>
<p><b>Recommendations</b></p>	<p>I.3 NHS GGC to ensure there are processes in place to facilitate the tracking of individual SACT drugs released from pharmacy.</p> <p>I.4 All boards across the MSN CYPC should undertake regular auditing and monitoring of the following aspects of safe administration within their SACT Governance Groups to ensure compliance with CEL30 (2012):</p> <ul style="list-style-type: none"> <li>• 2 nurse independent checks</li> <li>• documentation of batch numbers</li> <li>• documentation of expiry dates and</li> <li>• documentation of administration times for both SACT and supportive medications.</li> </ul>

<b>Section J. Administration of intravenous SACT includes techniques to minimise risk of extravasation [1] and procedures for management of the suspected or actual extravasation (CEL 30 (2012) standard 6) [1] Leakage of an intravenous medicine from the vein into surrounding tissues.</b>	
<b>Findings – Adult SACT Services</b>	All sites report full compliance with all aspects of Section J.
<b>Recommendations</b>	Not applicable.
<b>Findings – Children and young people’s SACT service</b>	NHS Tayside and NHS Lothian have identified that their local extravasation policies require review, update, and approval.
<b>Recommendations</b>	J.1 NHS Tayside and NHS Lothian to ensure their extravasation guidelines are review, updated, approved and easily accessible to clinical staff.

<b>Section K. The patient is assessed for adverse effects at appropriate intervals using a recognised toxicity grading system (CEL 30 (2012) standard 3.1.5 &amp; 5.1.6)</b>	
<b>Findings – Adult SACT Services</b>	<p>With regards to SACT toxicity documentation there appears to be themes identified within the CEL30 audit returns these are:</p> <ul style="list-style-type: none"> <li>• Inconsistencies or differences in robust mechanisms for pre-SACT prescribing documentation of toxicities (e.g. some paper toxicity documentation, some clinical letters, some clinical notes on FormStream or equivalent and some on ChemoCare).</li> <li>• Access to appropriate IT systems for all members of the MDT.</li> <li>• Missing Toxicity assessments in outpatient setting.</li> <li>• Pre-SACT administration toxicities appear to be better documented however there are again differences in how this is documented. E.g., documented on paper, scanned, and uploaded at each cycle, documented on FormStream (SACT Booklet template) or SACT Checklist / Flowchart in use).</li> </ul> <p>It has also been identified that some areas are developing SOPs for telephone consultations and some areas have identified that this method of assessment is currently covered by existing policies.</p> <p>Aberdeen Royal Infirmary has advised that they are undertaking work via SLWGs covering: booking/scheduling; pre-assessment; confirming of SACT (ensuring consistent recording of PS, location of</p>

	<p>documentation of patient specific SACT information, improving efficiency and streamlining of SACT prescribing, preparation and timely correspondence to GPs).</p> <p>Dr Gray's Elgin have identified a requirement to review local governance processes and where responsibilities lie. This will be strengthened, with the development of a co-operative governance arrangement providing additional support for the nursing team.</p>
<b>Recommendations</b>	<p>K.1 All boards should have a SOP detailing the required pre-SACT toxicity documentation, this should include:</p> <ul style="list-style-type: none"> <li>• Who can undertake toxicity assessment and what training has been provided.</li> <li>• Where toxicities will be documented for each tumour specific prescribing and administration team, specifying the method of documentation e.g. Toxicity check sheet; clinic letter; FormStream (or equivalent entry) or ChemoCare entry.</li> </ul> <p>K.2 All boards should ensure all members of the SACT prescribing, verification and administration team have access to pre-SACT toxicity assessments.</p>
<b>Findings – Children and young people's SACT service</b>	<p>Aberdeen Children's Hospital within NHS Grampian highlighted that toxicity assessment/clinic review by senior medical staff was not compliant in some patient records. However, a plan is now in place for patients to be reviewed clinically prior to each cycle of SACT and Consultants to document toxicities on ChemoCare.</p> <p>NHS Lothian reported issues with the consistency of toxicity scoring and have taken this forward as part of their action plan.</p> <p>NHS GGC have reported issues with inconsistencies in the documentation of the rationale for SACT treatment modifications during the patient record reviews. Processes are currently being reviewed and will be formalised with an updated SOP.</p>
<b>Recommendations</b>	<p>K.3 NHS Grampian and NHS Lothian should have a SOP detailing the required pre-SACT toxicity documentation, this should include:</p> <ul style="list-style-type: none"> <li>• Who can undertake toxicity assessment and what training has been provided.</li> <li>• Where toxicities will be documented for each tumour specific prescribing and administration team, specifying the method of documentation e.g. Toxicity check sheet; clinic letter; FormStream (or equivalent entry) or ChemoCare entry.</li> </ul>

	K.4 NHS GGC to provide assurance that an SOP has been developed to ensure consistency in the documentation of the rationale for SACT dose modifications.
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<b>Section L. Adverse effects are being managed appropriately (CEL 30 (2012) standards 2.2 &amp; 7.2)</b>	
<b>Findings – Adult SACT Services</b>	All sites report full compliance with all aspects of Section L.
<b>Recommendations</b>	Not applicable.
<b>Findings – Children and young people’s SACT service</b>	Full compliance was reported with all aspects of section L.
<b>Recommendations</b>	Not applicable.

<b>Section M. All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed and learning shared (CEL 30 (2012) standard 1.3.3)</b>	
<b>Findings – Adult SACT Services</b>	Queen Margaret Hospital and Victoria Hospital within NHS Fife noted that although review and shared learning of incidents was achieved regionally via the Cancer Therapeutics Advisory Committee that an improved mechanism to ensure shared learning locally was required.
<b>Recommendations</b>	<p>M.1 NHS Fife to confirm that processes are in place to ensure local shared learning of adverse events.</p> <p>M.2 RCNs should facilitate regular meetings with representation from their constituent boards to identify regional shared learning opportunities.</p> <p>M.3 HIS alongside regional network stakeholders to explore a process to share learning opportunities from SACT related clinical incidents (outstanding action from 2017).</p>
<b>Findings – Children and young people’s SACT service</b>	Full compliance was reported with all aspects of section M.
<b>Recommendations</b>	M.4 The MSN CYPC should facilitate regular meetings with representation from all boards to identify national shared learning opportunities.

<b>Section N. Intrathecal cytotoxic chemotherapy is delivered safely (CEL 21 (2009))</b>	
<b>Findings – Adult SACT Services</b>	Most boards reported full compliance with all aspects of Section N except for the Queen Elizabeth Hospital within NHS GGC who reported poor compliance with completion of intrathecal SACT prescriptions.
<b>Recommendations</b>	N.1 Queen Elizabeth Hospital, NHS GGC to confirm that appropriate actions have been taken to ensure compliance with the full completion of intrathecal SACT prescriptions and ongoing monitoring is in place.
<b>Findings – Children and young people’s SACT service</b>	Full compliance was reported with all aspects of section N.
<b>Recommendations</b>	Not applicable.

<b>Section O. All staff involved in SACT delivery have the appropriate skills, knowledge and training (CEL 30 (2012) standard 1.2.1)</b>	
<b>Findings – Adult SACT Services</b>	<p><b>Nursing:</b> Overall nursing compliance with SACT training is compliant with CEL30 (2012). Issues have been raised about the allocation of protected time for staff to undertake this training and ensuring appropriate reconciliation of training records. The introduction of the UKONs SACT passport and annual updates provided via LearnPro and / or face to face annual updates has assisted in the standardisation of nursing training. Challenges have been identified where nursing staff are working across mixed specialties i.e., inpatient SACT provision out with cancer centres.</p> <p><b>Pharmacy:</b> Most boards report in-house training for pharmacists across Scotland which is based upon a training plan developed by the Scottish Oncology Pharmacy Practice Group and enhanced by revalidation processes as part of GPhC revalidation requirements. Pharmacy technicians undertake local training relevant to roles undertaken. It is noted that BOPA has recently launched a National SACT Verification passport similar to nursing training in this area.</p> <p><b>Medical (Oncology / Haematology):</b> Consultant medical staff are assumed to be compliant, and this is currently being evidenced as having PDR’s undertaken. Specialty Doctors education and training is assumed to be compliant via weekly protected learning time; PDR’s; prescribing review</p>

	<p>processes mini-CEX, case-based discussion, however it is acknowledged that there is a lack of formalised documentation reported.</p> <p><b>Junior Doctors (working within oncology / haematology):</b> Although junior medical staff are not directly involved in the prescribing of SACT, they are often involved in the assessment and management of SACT related toxicities, hypersensitivity reactions and extravasation. Currently there is a lack of standardised documentation of this training across Scotland although some boards do report dedicated time within junior doctor teaching sessions.</p> <p><b>Junior Doctors (working out with oncology / haematology e.g. CAU; ED):</b> Although junior medical staff working out with oncology / haematology are not directly involved in the prescribing of SACT, they are often involved in the assessment and management of SACT related toxicities and Acute Oncology Management. Currently there is a lack of standardised documentation of this training across Scotland although some boards do report dedicated time within junior doctor teaching sessions and inter department training sessions within e.g. CAU / ED.</p> <p><b>Ancillary (Domestic and Portering):</b> Formalised training records for ancillary staff is variable across Scotland. There is no standardised template for this and there potentially needs to be an agreed structure for educational responsibility feeding into the line management structure.</p>
<p><b>Recommendations</b></p>	<p>O.1 All boards should continue to support the roll out of the UKONs SACT Passport and competency framework.</p> <p>O.2 All boards should continue to strengthen documentation of pharmacy training records. The BOPA electronic SACT Verification passport to record competency should be considered for routine adoption across Scotland.</p> <p>O.3 All boards should ensure that there are systems in place, which provide specific reassurance that medical staff at trainee and specialty doctor level have the appropriate skills, knowledge and training required.</p> <p>O.4 All boards should ensure that there are systems in place which provide specific reassurance that junior medical staff have the appropriate skills, knowledge and training required to assess and manage SACT toxicities, acute oncology presentations and safe</p>

	<p>handling of SACT principles on commencing a post / rotation within oncology / haematology.</p> <p>O.5 All boards to ensure that ancillary staff have had clear formalised training and have documentation of this being undertaken.</p>
<p><b>Findings – Children and young people’s SACT service</b></p>	<p>All boards across the MSN CYPC reported being fully compliant with section O, with the exception of NHS Grampian.</p> <p>Aberdeen Children’s Hospital within NHS Grampian have reported that pre-SACT toxicity assessments are completed by junior doctors (FY1 to senior StR trainees, with the support of on-call and named consultants). The junior medical staff are provided with instruction on pre-SACT assessment as part of their induction to oncology / haematology. The junior medical staff have started using SACT specific guides to assess toxicities, however, have no formal documentation of pre-SACT assessment competencies for junior medical staff.</p> <p>In addition, NHS Grampian identified that there was a need to provide adequate protected time to train medical and pharmacy staff. It is noted that there is now a full-time pharmacist in post who will train other members of the team using the new Paediatric Oncology Pharmacy (POP) training programme by March 2024.</p>
<p><b>Recommendations</b></p>	<p>O.6 NHS Grampian should ensure that there are systems and competency assessments in place which provide specific reassurance that junior medical staff have the appropriate skills, knowledge and training required to assess patients’ toxicities prior to SACT.</p> <p>O.7 All boards across the MSN CYPC should support the roll out of the Children’s Cancer and Leukaemia Group (CCLG) SACT Passport and competency framework.</p> <p>O.8 All boards should continue to strengthen documentation of pharmacy training records. The BOPA electronic SACT Verification passport to record competency should be considered for routine adoption across Scotland.</p> <p>O.9 All boards should ensure that there are systems in place which provide specific reassurance that medical staff at trainee, staff grade and specialty doctor level have the appropriate skills, knowledge and training required.</p>

	<p>O.10 All boards should ensure that there are systems in place which provide specific reassurance that junior medical have the appropriate skills, knowledge and training required to assess and manage SACT toxicities, acute oncology presentations and safe handling of SACT principles on commencing a post / rotation within oncology / haematology.</p> <p>O.11 All boards to ensure that ancillary staff have had clear formalised training and have documentation of this being undertaken.</p>
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## Next steps

HIS expects each regional cancer network, their constituent NHS boards and the MSN CYPC, through their SACT clinical leads, to address outstanding gaps in compliance against the standards and implement the recommendations. Healthcare Improvement Scotland will request a report on progress to be submitted by the RCNs and MSN CYPC within 18 weeks of the publication of this report.

There are also national recommendations for Healthcare Improvement Scotland, the Scottish Cancer Network, and the SACT programme Board to consider. The SACT Programme Board is requested to consider taking the lead on work to develop nationally consistent methodology to review, monitor and report SACT Capacity and Workforce issues as part of the Scottish Government Oncology Transformation Work Programme. HIS will also facilitate meetings with representation from RCNs to identify national shared learning opportunities for SACT related clinical incidents of avoidable harm and near miss events.

Following the recent publication of the 2023 [\[Revised\] Guidance for the safe delivery of systematic anti-cancer therapy \(scot.nhs.uk\)](https://www.scot.nhs.uk/clinical-standards/2023-revised-guidance-for-the-safe-delivery-of-systematic-anti-cancer-therapy) the HIS SACT Governance Leads, alongside RCN and MSN stakeholders, will undertake a review of the SACT governance framework, and associated tools to identify the most appropriate approach to ongoing assurance of SACT services considering lessons learned from this audit cycle. Following the review, Healthcare Improvement Scotland will publish the revised framework and tools, provide training, and agree appropriate timescales for completion of any future audits to support ongoing assurance of SACT services.

## Ongoing governance arrangements for Systemic Anti-Cancer Therapy services

Until revised guidance following the publication of the 2023 CEL30 (2012) refresh is provided by Healthcare Improvement Scotland, all three regional cancer networks, NHS boards and MSN CYPC will continue to progress all outstanding actions and take forward recommendations from this report.

The regional cancer networks, NHS boards and MSN CYPC have arrangements in place at a national (MSN CYPC), regional and local level to ensure the ongoing monitoring of compliance with CEL 30 (2012) and have demonstrated ongoing commitment to future reporting:

- Within the North Cancer Alliance (NCA), all the mainland NHS boards have established SACT governance arrangements and have nominated SACT clinical leads. Within these existing NHS board structures there are arrangements (and nominated individuals) for delivering, improving, and maintaining compliance in partnership with the multiple SACT satellite sites across NCA. The NCA SACT Governance Group is responsible for regional scrutiny and reporting upwards to the NCA Operational Delivery Group on progress.
- Within the South East Scotland Cancer Network (SCAN), ongoing monitoring of action plans and audit results will be carried out through the Chemotherapy Advisory Group. This group will report to the Regional Cancer Planning Group and the RCAG on a quarterly basis to provide information on outstanding actions and improvement plans.
- Within the West of Scotland Cancer Network (WoSCAN), ongoing quality assurance and governance of SACT services will be provided by NHS boards' local clinical governance and SACT groups. Action plans created following the initial audit visits will continue to be monitored by the Regional SACT Executive Steering Group.
- Within the Managed Service Network for Children and Young People with Cancer (MSN CYPC), the MSN CYPC will ensure ongoing monitoring of action plans from each of the treatment centres via the MSN CYPC Clinical Governance Group. This group will meet and review action plans on a quarterly basis to provide information on outstanding actions and improvement plans.
- Healthcare Improvement Scotland will continue to engage with stakeholders to ensure that following the 2023 CEL30 (2012) refresh that the governance framework, audit tools and review processes are refreshed. This includes ensuring that the SACT audit tools take full account of the differences in approach to the provision of SACT services for children and young people with cancer.

## Appendix 1: Overview of the NHS Boards and Sites within each RCN / MSNCYPC in NHS Scotland

North Cancer Alliance (NCA)	South East Scottish Cancer Network (SCAN)
<p><b>NHS Grampian Sites:</b> Aberdeen Royal Infirmary Dr Gray's Hospital (Elgin)</p> <p><b>NHS Orkney Site:</b> The Balfour Hospital (Orkney)</p> <p><b>NHS Shetland Site:</b> Gilbert Bain Hospital (Shetland)</p> <p><b>NHS Highland Sites:</b> Raigmore Hospital (Inverness) Peripheral sites: Caithness General Hospital (Wick); Broadford Hospital (Skye); Belford Hospital (Fort William); Lorn &amp; Islands Hospital (Oban) Mid Argyll Community Hospital (Lochgilphead)</p> <p><b>NHS Western Isles Site:</b> Western Isles Hospital (Stornoway)</p> <p><b>NHS Tayside Sites:</b> Ninewells Hospital (Dundee) Perth Royal Infirmary</p>	<p><b>NHS Borders Site:</b> Borders General Hospital (Melrose)</p> <p><b>NHS Dumfries &amp; Galloway Site:</b> Dumfries &amp; Galloway Royal Infirmary (Dumfries)</p> <p><b>NHS Fife Site:</b> Queen Margaret Hospital (Dunfermline) Victoria Hospital (Kirkcaldy)</p> <p><b>NHS Lothian Site:</b> Edinburgh Cancer Centre St John's Hospital (Livingston) Royal Infirmary Edinburgh</p>
West of Scotland Cancer Network (WoSCAN)	Managed Service Network Children & Young People with Cancer (MSN CYPC)
<p><b>NHS Ayrshire &amp; Arran Sites:</b> University Hospital Crosshouse (Kilmarnock) Kyle SACT Day Unit, Ailsa Campus (Ayr)</p> <p><b>NHS Forth Valley Site:</b> Forth Valley Royal Hospital (Larbert)</p> <p><b>NHS Greater Glasgow &amp; Clyde Sites:</b> Beatson West of Scotland Cancer Centre (Glasgow) Queen Elizabeth Hospital (Glasgow) New Victoria Hospital (Glasgow) New Stobhill (Glasgow) Royal Alexandra Hospital (Paisley) Glasgow Royal Infirmary (Glasgow) Inverclyde Royal Hospital (Inverclyde) Vale of Leven (Alexandria)</p> <p><b>Lanarkshire Sites:</b> University Hospital Wishaw (Wishaw) University Hospital Monklands (Airdrie) University Hospital Hairmyres (East Kilbride)</p>	<p><b>NHS Greater Glasgow &amp; Clyde Site:</b> Royal Hospital for Children (Glasgow)</p> <p><b>NHS Grampian Site:</b> Royal Aberdeen Children's Hospital</p> <p><b>NHS Highland Site:</b> Raigmore Hospital (Inverness)</p> <p><b>NHS Lothian Site:</b> Royal Hospital for Children &amp; Young People Edinburgh</p> <p><b>NHS Tayside Site:</b> Ninewells Hospital (Dundee)</p>

## Appendix 2: Attenuated audit approach

### Communication from HIS to RCNs and MSN November 2022

#### Part 1: Provision of an update on progress to date

**The purpose of this part of the request was to provide HIS with an update of progress to date only, no additional audit activities were required to return this information.**

Regional cancer networks (RCNs) and the Managed Service Network for Children and Young People with Cancer (MSN CYPC) were asked to provide information on CEL30 (2012) audits undertaken during the current audit cycle from January 2019 to date. The information required included:

- Detail by board, of what board / site audits had been carried out to date, the dates these were carried out, and whether these were internal only or if an external audit had been completed prior to the pause in the programme. If no audits have been carried out for individual boards and/ or sites please also provide this information.
- A copy of the Board Assessment Summary Report, and Individual Site Assessment Summary Report for each audit carried out. If an external audit has been carried out please provide the summary report related to this, if only internal audits have been carried out to date please provide the summary outcomes page for these.
- In addition the board and individual site action logs should be provided detailing any relevant actions which have been devised to address identified areas of improvement, with timescales for resolution identified, if not yet completed.
- The deadline for return of this information was set as Monday 16<sup>th</sup> January 2023.

#### Part 2: Completion of Audit Cycle (Deadline Friday 31<sup>st</sup> March 2023)

- For any boards and sites where internal board and / or site audits had not been carried out prior to the pause in the audit programme, the boards were asked to undertake these.
- For boards and sites where an external audit had not been completed prior to the pause in the audit programme, the RCN SACT Governance Group / MSN CYPC SACT Group were asked to review submitted board and site internal audit reports and facilitate regional internal validation of the CEL30 (2012) audits by utilising peer auditors from within their own regional network only. This could be undertaken virtually and did not necessitate a full external audit site visit.
- In addition, we requested that all boards identify any changes and / or developments made within SACT services since their internal / external audit was completed and undertake review of these to ensure continued compliance with CEL 30 standards#. For example, any changes implemented in response to the COVID-19 pandemic, which were still in place such as virtual clinic arrangements for SACT, oral SACT delivery arrangements or a change in SACT delivery areas\* / models.
- The RCNs / MSN CYPC were asked to return a copy of the validated Board Assessment Summary Report, and individual Site Assessment Summary Report for each audit carried

out, detailing what level of review was undertaken for each audit i.e. who undertook the review, whether it was a formal external audit or regional peer review, whether virtual or in person. Accompanying board and individual site action logs, which were devised to address identified areas of improvement, with timescales for resolution identified or confirmation of resolution, were also requested.

- *#Appendix 1: Health Board information to changes and / or developments to SACT services throughout the Covid-19 Pandemic*
- *\*Appendix 2: A risk assessment tool to facilitate assessment of SACT administration areas*
- Services were asked to feedback information on areas identified, with assurance of compliance, any identified exception reports and related action plans by 31<sup>st</sup> March 2023.

### **HIS Review and Feedback**

- HIS committed to undertaking an informal review of the submitted reports.
- A report will be produced by the end of June 2023 (delayed until Sept 2023 due to delays in return of information), and feedback will be provided to each RCN and the MSN. HIS will then publish the main themes identified from the attenuated audit cycle.
- A national SACT stakeholder shared learning event will be hosted by HIS to provide feedback on the informal CEL30 (2012) audit cycle and allow RCNs a national platform to share examples of innovative changes to SACT services identified through the audit process, that may inform future SACT service developments across Scotland.



## Appendix 3: Additional Information Requested from WoSCAN Sites in Absence of Peer Review

### Individual Site Assessment Audit Tool

#### Additional Information to be Provided in Absence of Peer Review Process (WoSCAN sites)

NHS Board:	
Site/clinical area:	
Date assessment conducted:	
Board assessment team (add rows as required)	
Name (lead assessor):	Designation:
Name:	Designation:
Name:	Designation:
Name:	Designation:
<b>A. Clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) are readily available to all clinical staff involved in the delivery of SACT (CEL 30 (2012) standards 1.4,1.5 &amp; 7.1)</b>	
<ol style="list-style-type: none"> <li>1. For completion of this section provide an overview of how many staff were spoken to and breakdown of their role, experience level (where possible) and area of responsibility:</li>   <li>2. What questions / clinical scenarios did you ask staff to establish their knowledge base?</li> </ol>	
<b>Completion of individual patient record review questions 1-11</b>	
B. The decision to initiate a new course of SACT is taken by a consultant oncologist / haematologist (CEL 30 (2012) standard 2.1.5)	
C. The patient has provided written informed consent to receive SACT (CEL 30 (2012) standards 2.1.4 & 2.2.1)	
D. The performance status of the patient is documented (CEL 30 (2012) standards 2.1.6 & 3.1.6)	
E. SACT is prescribed correctly (CEL 30 (2012) standard 3)	
F. SACT is verified correctly (CEL 30 (2012) standard 4.1)	
I. Safe administration of SACT (CEL standards 5.1.3, 5.1.5, 5.1.6, 5.2)	

K. The patient is assessed for adverse effects at appropriate intervals using a recognised toxicity grading system (CEL 30 (2012) standard 3.1.5 & 5.1.6)

Provide information on how many case notes were reviewed in total (were these paper or electronic) : **Total =**

- For each individual patient record review please provide summary breakdown of:
  - diagnosis
  - treatment intent
  - SACT treatment area - in-pt, day case & or OP Clinic (F2F or virtual)

And where possible:

- route - breakdown of oral, IV, s/c
- line of treatment
- number of cycles received (expectation being min of 3 cycles)

**E. SACT is prescribed correctly (CEL 30 (2012) standard 3)**

List of practitioners appropriately qualified and trained to prescribe SACT (medical and non-medical prescribers) is available to all staff

1. Provide information on where this list is kept, and process for update:
2. Provide information on staff groups questioned to provide evidence that there is an awareness of where to locate this for reference:

**G. SACT prepared and dispensed correctly (CEL 30 (2012) standards 4.2.1-4, 4.3 & 4.4)**

Procedures for the safe dispensing and release of SACT from a pharmacy controlled facility

1. For completion of this section provide an overview of the staff that were spoken to and breakdown of their role, experience level (where possible) and area of responsibility:
2. What questions did you ask staff to establish their knowledge base?

<b>H. Areas used for SACT administration are safe and appropriate (CEL standard 5.1.2, 5.1.4, 6.2.2, 9.4.2)</b>	
Current risk assessments of areas where SACT is administered	<ol style="list-style-type: none"> <li>1. Provide an overview of areas where SACT is administered on the site:</li> <li>2. List treatment areas reviewed on the site as part of the self-assessment and confirm risk assessment for these areas administering SACT was undertaken:</li> </ol>
<b>J. Administration of intravenous SACT includes techniques to minimise risk of extravasation [1] and procedures for management of the suspected or actual extravasation (CEL 30 (2012) standard 6) [1] Leakage of an intravenous medicine from the vein into surrounding tissues.</b>	
Discuss with staff on understanding of policy & awareness of location of extravasation kits	<ol style="list-style-type: none"> <li>1. For completion of this section provide an overview of how many staff were spoken to and breakdown of their role, experience level (where possible) and area(s) where they work:</li> <li>2. What questions / clinical scenarios did you ask staff to establish their knowledge base?</li> </ol>
<b>K. The patient is assessed for adverse effects at appropriate intervals using a recognised toxicity grading system (CEL 30 (2012) standard 3.1.5 &amp; 5.1.6)</b>	
Review of local patient/care pathways	<p>Confirmation of review process for this point:</p> <ul style="list-style-type: none"> <li>• highlight if toxicity assessment tool is used, and if this is paper or electronic or</li> <li>• toxicities are transcribed freehand in clinical letters or clinical IT systems</li> </ul>
<b>L. Adverse effects are being managed appropriately (CEL 30 (2012) standards 2.2 &amp; 7.2)</b>	
Review of local patient/care pathways	Confirmation of review process for this point and pathways available for review and admission as appropriate.
<b>M. All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed and learning shared (CEL 30 (2012) standard 1.3.3)</b>	

Staff awareness of clinical incident process	<ol style="list-style-type: none"> <li>1. For completion of this section provide an overview of how many staff were spoken to and breakdown of their role, experience level (where possible) and area of responsibility:</li> <li>2. What questions did you ask staff to establish their knowledge base?</li> </ol>
Example of documented event/near miss	Please provide an example and / or critical incident report which gives an overview of process – for example clinical safety briefings or newsletters to ensure shared learning:
<b>N. Intrathecal cytotoxic chemotherapy is delivered safely (CEL 21 (2009))</b>	
Staff awareness of policy and understanding of process	For completion of this section provide an overview of how many staff were spoken to and breakdown of their role, and experience level:
Review 2 intrathecal prescriptions	Confirm that intrathecal administration takes place on site, and if so that both prescriptions were fully compliant:
<b>O. All staff involved in SACT delivery have the appropriate skills, knowledge and training (CEL 30 (2012) standard 1.2.1)</b>	
Review cross section of staff training records to ensure practice remains up to date and relevant	How many training records did you review for each discipline of staff, what grade / level of experience did they have and what specific training / competency records were you looking for?
<b>ADDITIONAL INFORMATION</b>	
Were any issues / concerns raised by any members of staff regarding SACT service during the audit, which are notable, and if yes, please specify:	

## Appendix 4: SACT Service Delivery – Assessment tools evidence examples

### Board Assessment Tool Evidence Examples:

<b>1. The NHS board has identified a Lead Clinician for SACT services (a consultant oncologist or haematologist) and documented their roles and responsibilities. They are supported by a senior pharmacist and a senior nurse (CEL 30 (2012) standards 1.1.3 – 1.1.7)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Evidence of appointment</b>	
<b>2. Reporting structure</b>	
<b>3. Lead Clinician’s job plan including details of roles and responsibilities</b>	
<b>4. Cooperative governance arrangement where Lead Clinician is employed outside the NHS Board area</b>	Demonstrate that the Lead Clinician is truly part of the Board’s governance processes, has the appropriate authority and is integral to local strategic and operational SACT governance, processes and communications. Evidence could include: letter of appointment, job plan from parent Board, communications and meeting papers.
<b>5. Named senior nurse</b>	
<b>6. Named senior pharmacist</b>	
<b>7. Current annual report to the appropriate NHS Board clinical governance group</b>	
<b>2. Capacity and workforce plans for SACT services are available and are reviewed and reported on a regular basis (CEL 30 (2012) standard 1.3.2)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Current capacity and workforce plan</b>	The board is compliant if there is evidence of strategic oversight, pressures of delivering the service are identified and governance processes exist: <ul style="list-style-type: none"> <li>• Review the risk register for examples of SACT issues relating to capacity, staffing, treatment delays, turn around</li> <li>• DATIX reports on treatment delays</li> <li>• Review complaints log relating to SACT services</li> </ul>

	<ul style="list-style-type: none"> <li>• Minute of cancer management team meetings</li> </ul>
<b>2. Evidence of review by senior managers and the appropriate clinical governance group</b>	<ul style="list-style-type: none"> <li>• Minutes of governance meetings reviewing risks</li> <li>• Evidence may include escalation by the local SACT group to its parent group.</li> </ul>
<b>3. There are clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) in place (CEL 30 (2012) standards 1.1.8, 1.4, 1.5, 7.1 and Best Practice statement for Assessment, Diagnosis and Management of Neutropenic Sepsis: SGHD Sep 2011)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Co-ordinated approach in place for development, approval and review:</b> i. CMGs ii. SACT Protocols iii. STGs	<ul style="list-style-type: none"> <li>• Best practice is a network approach</li> <li>• A Board level approach may be more appropriate for certain guidelines e.g. neutropenic sepsis</li> <li>• SOP/ framework document/terms of reference for relevant groups</li> <li>• Examples of CMGs/SACT protocols/STGs</li> <li>• Although not specified in CEL 30 (2012) it is now considered good practice to have guidance on managing Immunotherapy related adverse events</li> <li>• SACT protocols should be checked for compliance with the framework outlined in CEL 301 (2012) (see SACT Protocols checklist tab).</li> </ul>
<b>2. Contingency plan in case of electronic system failure in relation to SACT</b>	<ul style="list-style-type: none"> <li>• Approved contingency plan and communication of this plan to relevant staff</li> <li>• Includes access to SACT electronic prescribing system and access to SACT protocols.</li> </ul>
<b>4. The decision to initiate a new course of SACT is taken by a consultant oncologist / haematologist and the patient has provided written informed consent to receive SACT (CEL 30 (2012) standard 2.1)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. NHS Board policy for consent to receive SACT</b>	
<b>2. Availability of standardised documentation for consent to treatment</b>	
<b>3. NHS Board policy for initiating SACT treatment</b>	
<b>5. SACT is prescribed, verified, prepared and administered correctly (CEL 30 (2102) standards 3, 4.2.5-6, &amp; 5)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. SACT medical and non-medical prescribing policy</b>	All policy and procedure documents reviewed during the audit process are checked for evidence of ownership, approval by the appropriate governance

	groups, version control, validity and review period. The audit team are not expected to judge content of policies but may note an issues identified as observations.
<b>2. List of practitioners appropriately qualified and trained to prescribe SACT (medical and non-medical prescribers) is available to all staff</b>	There may be different methods applied by Boards for maintaining this information e.g. a report from Chemocare listing prescribers may be acceptable if the process for accessing prescribing rights on Chemocare includes evidencing appropriate training.
<b>3. Policy/protocol for key pharmaceutical checks</b>	Ref: CEL 30 (2012) Appendix 3, provided in 'key pharmaceutical checks' tab.
<b>4. Dispensing policies</b>	
<b>5. Policies for SACT administration (including oral)</b>	
<b>6. Aseptic facilities within Board have undergone external audit within the last 2 years and an action plan is in place</b>	Check audit reports and action plans.
<b>6. All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed, and learning shared (CEL 30 (2012) standard 1.3.3)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. NHS Board incident management policy and investigation process</b>	Duty of Candour is incorporated into policy. If available, provide example of SACT incidence in the organisation where Duty of Candour was applied.
<b>2. System(s) for:</b> <b>i. documenting and reviewing clinical incidents of avoidable harm and near miss events</b>	For example, Datix system which has a SACT related flag incorporated to facilitate collating SACT related clinical incidents.
<b>ii. documenting actions taken / changes made as a result of incident reports</b>	For example, Datix system which has a SACT related flag incorporated to facilitate collating SACT related clinical incidents.
<b>iii. Clinical Governance Committee review of clinical incidents</b>	
<b>3. Evidence of sharing learning</b>	Shared learning, at board or regional level, of an incident (cross reference Site Assessment M Clinical incidents reviewed and learning shared at local level) Evidence of review of extravasation events.

<b>7. Administration of intravenous SACT includes techniques to minimise risk of extravasation* and procedures for management of the suspected or actual extravasation (CEL 30 (2012) standard 6)</b>	
<b>*[1] Leakage of an intravenous medicine from the vein into surrounding tissues.</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Extravasation policies / procedures for:</b>	
<b>i. prevention</b>	Up to date patient information leaflets – on the risk of extravasation issued pre-treatment and on management of extravasation for use in the event of extravasation.
<b>ii. treatment</b>	
<b>iii. follow-up management</b>	
<b>iv. communication with GP</b>	GP letter template.
<b>8. Intrathecal cytotoxic chemotherapy is administered safely (CEL 21 (2009))</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Intrathecal Policy</b>	
<b>2. Intrathecal register held by the Chief Executive and copies held by the designated lead for the NHS board, Medical Director, Director of Pharmacy and Director of Nursing</b>	View register.
<b>9. Death within 30 days is reported and reviewed (CEL 30 (2012 standard 1.3.4))</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Procedures/protocols for documenting, reporting and reviewing all deaths occurring within 30 days of SACT administration</b>	Consideration to how deaths are captured to facilitate complete identification by whatever means possible. Recognise that there may be small number of patients who will not be captured.
<b>2. Minutes of clinical governance meetings where reports are discussed</b>	Minutes from relevant MDT and Morbidity and mortality meetings are acceptable.
<b>3. Example of a mortality case review</b>	1 or more completed patient proforma.
<b>10. All staff have the appropriate skills, knowledge and training (CEL 30 (2012 standard 1.2.))</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>1. Education and training programme</b>	There will be evidence of a systematic approach to training:

<p><b>(see CEL 30 (2012) 1.2.3) including competencies and methods of assessments</b></p>	<ul style="list-style-type: none"> <li>• Encompasses all those involved in the delivery of SACT services including transport of SACT: medical, nursing, pharmacy, ancillary and portering staff</li> <li>• Process for educating staff on a new medicine</li> <li>• Process for training new staff</li> <li>• List of participants in training programmes</li> <li>• Examples of signed training plans</li> <li>• Consider non-specialist staff e.g. A&amp;E/medical receiving training on managing acute toxicities</li> <li>• Consider specialised staff in non-training roles e.g. experienced staff grades/locum consultants with prior experience. Such individual may have required expertise but not fit easily into established systems of competency assessment.</li> </ul>
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**Individual Site Assessment Tool Evidence Examples:**

<b>A. Clinical management guidelines (CMGs), SACT protocols and associated supportive treatment guidelines (STGs) are readily available to all clinical staff involved in the delivery of SACT (CEL 30 (2012) standards 1.4,1.5 &amp; 7.1)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Accessibility to all relevant clinical staff and awareness of CMGs, SACT protocols &amp; supportive treatment guidelines</b>	<ul style="list-style-type: none"> <li>• Doctors, nurses and pharmacists delivering SACT services can demonstrate access to, up to date, documents on the intranet site or paper copies</li> <li>• These staff can describe process for review and implementation of a new guidelines including, how this is communicated</li> <li>• Regional audit team to search for guidelines relevant to the case records being reviewed.</li> </ul>
<b>Guidelines for the management of complications of SACT, in particular, neutropenic sepsis &amp; immunotherapy related adverse effects, are accessible to all relevant staff across the NHS Board area e.g. acute assessment units</b>	<ul style="list-style-type: none"> <li>• Staff to show how they would access protocols and guidelines</li> <li>• neutropenic sepsis in line with the Best Practice statement for Assessment, Diagnosis and Management of Neutropenic Sepsis: Scottish Government September 2011</li> <li>• nausea and vomiting</li> <li>• diarrhoea and constipation</li> <li>• mucositis</li> <li>• skin toxicity</li> <li>• tumour lysis syndrome</li> <li>• hypersensitivity reactions</li> <li>• immunotherapy related adverse events guidance.</li> </ul>
<b>Contingency plan when system failure (e.g. computer system failure) and how to manage a backlog of activity</b>	<ul style="list-style-type: none"> <li>• Local team to outline contingency plans and how guidelines are accessed</li> <li>• Questioning of staff in clinical area(s) on access to guideline/contingency plans</li> <li>• Ensure staff can ID key personnel that would manage any issues within the site.</li> </ul>
<b>B. The decision to initiate a new course of SACT is taken by a consultant oncologist / haematologist (CEL 30 (2012) standard 2.1.5)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review questions 1 – 5</b>	<ul style="list-style-type: none"> <li>• Clear documentation of the decision by the consultant</li> <li>• The management plan is clear and unambiguous</li> <li>• MDT review for all first presentations for that cancer</li> </ul>

	<ul style="list-style-type: none"> <li>• If treatment difference from MDT recommendation, audit trail in patient record of rationale for the alternative treatment delivered and consultant involved in this decision</li> <li>• Treatment started before MDT review is clinically justified</li> <li>• GP communication within 14 days may not be possible in every circumstance e.g. if the patient is an inpatient.</li> </ul>
<b>C. The patient has provided written informed consent to receive SACT (CEL 30 (2012) standards 2.1.4 &amp; 2.2.1)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review questions 1 – 5</b>	<ul style="list-style-type: none"> <li>• A copy of written consent is available within the patient record</li> <li>• Consent has been taken by a consultant or an appropriate accredited medical trainee or non-medical prescriber</li> <li>• Documentation of verbal and written information given to patient</li> <li>• Consent to SACT is required in addition to consent to a clinical trial.</li> </ul>
<b>D. The performance status of the patient is documented (CEL 30 (2012) standards 2.1.6 &amp; 3.1.6)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review 6 &amp; 7</b>	<ul style="list-style-type: none"> <li>• Performance status at baseline is documented</li> <li>• Performance status is assessed within the time period defined by local Board policy for each treatment cycle/agreed interval and documented at time of prescribing. If two stop model, evidence of final assessment of patient fitness immediately prior to treatment.</li> </ul>
<b>E. SACT is prescribed correctly (CEL 30 (2012) standard 3)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>List of practitioners appropriately qualified and trained to prescribe SACT (medical and non-medical prescribers) is available to all staff</b>	Ask local team to provide list.
<b>Completion of individual patient record review question 7</b>	Check prescribers are included in the list of practitioners.
<b>F. SACT is verified correctly (CEL 30 (2012) standard 4.1)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>

<b>Completion of individual patient record review question 8</b>	<ul style="list-style-type: none"> <li>• Check prescription</li> <li>• Review of pharmaceutical care plans</li> <li>• Question pharmacist(s).</li> </ul>
<b>G. SACT is prepared and dispensed correctly (CEL 30 (2012) standards 4.2.1 -4, 4.3 &amp; 4.4)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Procedures for the safe dispensing and release of SACT from a pharmacy controlled facility</b>	<ul style="list-style-type: none"> <li>• Ensure there is clear guidance on dealing with SACT prescriptions – talk/ demonstrate through of processes for safe management of SACT dispensing and release.</li> <li>• Examine Procedures</li> <li>• Visit dispensary and question staff on awareness of SOPs and processes for dispensing and release.</li> <li>• Identify if cancer specific or general facility.</li> <li>• Demonstration of safe systems for issue of SACT i.e. no release unless authorised or demonstration of process that ensure administration cannot occur until authorisation if product released before this.</li> <li>• If pharmacy provides SACT to other sites ensure process for delivery to all sites is examined.</li> </ul>
<b>H. Areas used for SACT administration are safe and appropriate (CEL standard 5.1.2, 5.1.4, 6.2.2, 9.4.2)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Current risk assessments of areas where SACT is administered.</b>	<p>Site should have completed the ‘Risk assessment tool for areas that administer SACT’ within the last year</p> <p>Review risk assessment and assess how any risks are being managed and any mitigating circumstances. Consider overall patient safety.</p>
<b>I. Safe administration of SACT (CEL standard 5.1.3, 5.1.5, 5.1.6, 5.2)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review question 9</b>	Check prescribed date matches administration date.
<b>J. Administration of intravenous SACT includes techniques to minimise risk of extravasation* and procedures for management of the suspected or actual extravasation (CEL 30 (2012) standard 6) [1] *Leakage of an intravenous medicine from the vein into surrounding tissues.</b>	

<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Discuss with staff on understanding of policy &amp; awareness of location of extravasation kits</b>	<ul style="list-style-type: none"> <li>• Kit within date (within clinical areas).</li> </ul>
<b>Review an extravasation event identified on an incident reporting system (e.g. DATIX)</b>	<p>Examine the relevant patient's record for:</p> <ul style="list-style-type: none"> <li>• appropriate documentation of the incident along with a completed clinical incidents report</li> <li>• evidence of communication with the patient's GP</li> <li>• evidence of follow up and documented outcome</li> <li>• If unit cannot identify an extravasation spend time questioning staff on how they would manage an incident (could ask about a specific agent).</li> </ul>
<b>K. The patient is assessed for adverse effects at appropriate intervals using a recognised toxicity grading system (CEL 30 (2012) standard 3.1.5 &amp; 5.1.6)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review question 10</b>	
<b>Review of local patient/care pathways</b>	<p>Recognised toxicity grading system/tool in place.</p> <p>Completed toxicity assessments available in patient records.</p> <p>Discussion with clinical team on how adverse effects are managed including patient/care pathways, out of hours advice.</p> <p>Information given to patients.</p>
<b>L. Adverse effects are being managed appropriately (CEL 30 (2012) standards 2.2 &amp; 7.2)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Completion of individual patient record review question 11</b>	
<b>Review of local patient/care pathways</b>	<p>Review of adverse effects management in patient records.</p> <p>Discussion with clinical team on how adverse effects are managed including patient/care pathways, out of hours advice.</p> <p>Information given to patients.</p>
<b>M. All clinical incidents relating to SACT of avoidable harm and near miss events are documented, reviewed and learning shared (CEL 30 (2012) standard 1.3.3)</b>	

<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Staff awareness of clinical incident process</b>	
<b>Example of documented event/near miss</b>	Review examples including consideration of feedback process and dissemination of learning at local level (i.e. newsletters, safety briefs etc.) (cross-reference Board Assessment 6.3 Shared learning at Board or Regional level).
<b>N. Intrathecal cytotoxic chemotherapy is delivered safely (CEL 21 (2009))</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Staff awareness of policy and understanding of process</b>	Discussion with team and staff in clinical area.
<b>Review 2 intrathecal prescriptions</b>	100% compliance required: Check completeness of prescription and that all personnel involved with the process are listed on the intrathecal register i.e. prescriber, pharmacist, personnel issuing, receiving and administering the intrathecal.
<b>O. All staff involved in SACT delivery have the appropriate skills, knowledge and training (CEL 30 (2012) standard 1.2.1)</b>	
<b>EVIDENCE</b>	<b>EVIDENCE EXAMPLES</b>
<b>Cross section of staff training records to ensure practice remains up to date and relevant and review:</b>	Select from medical trainees/staff grades, all relevant pharmacy staff, nursing, ancillary and portering staff as appropriate for the site. Number of records will depend on size of the site. Details of training received, specialist clinical updates etc. Competency assessments if appropriate.

## Appendix 5: Collated Overview of Recommendations by Networks and Boards

Recommendation No:	Recommendation
<b>Recommendations across all Boards and Networks (Adult SACT Services)</b>	
1.4	All Boards - as recommended in the updated CEL30 (2023 revision) to ensure allocation of dedicated time for Pharmacy and Nursing SACT Leads, to undertake their responsibilities.
2.1	Key stakeholders to progress work to develop nationally consistent methodology to plan, review, monitor and report SACT capacity and workforce issues. It is requested that SACT programme Board consider taking forward a piece of work to address this recommendation, including consideration of a process to facilitate national oversight and escalation pathway for SACT capacity and workforce issues.
2.2	Appropriate reporting structures should be utilised for reporting SACT workforce and capacity issues locally / regionally and escalation plans developed.
3.1	RCNs to encourage engagement of clinicians and pharmacists in development of National Clinical Management Pathways (CMPs) via the SCN work programme to reduce duplication of effort in development and maintenance of these.
6.4	RCNs should facilitate regular meetings with representation from their constituent boards to identify regional shared learning opportunities
10.4	It would be beneficial to develop a nationally consistent template for documenting education provision and competency assessment for medical staff at specialty grade level and consultants who have trained outside of UK, to provide assurance that this group of staff have the appropriate skills, knowledge and training required to treat patient with SACT. The SACT Programme Board is asked to consider taking this forward.
H.2	All RCNs should review existing action plans from the completed risk assessments to ensure all appropriate actions have been addressed.
H.4	All boards and sites should ensure a self-assessment using the risk assessment tool is undertaken annually for all areas administering SACT and report into regional SACT groups.
I.2	All boards should undertake regular auditing and monitoring of the following aspects of safe administration within their SACT Governance Groups to ensure compliance with CEL30 (2012): <ul style="list-style-type: none"> <li>• 2 nurse independent checks</li> <li>• documentation of batch numbers</li> <li>• documentation of expiry dates and</li> <li>• documentation of administration times for both SACT and supportive medications.</li> </ul>

K.1	All boards should have a SOP detailing the required pre-SACT toxicity documentation, this should include: <ul style="list-style-type: none"> <li>• Who can undertake toxicity assessment and what training has been provided.</li> <li>• Where toxicities will be documented for each tumour specific prescribing and administration team, specifying the method of documentation e.g., Toxicity check sheet; clinic letter; FormStream (or equivalent entry) or ChemoCare entry.</li> </ul>
K.2	All boards should ensure all members of the SACT prescribing, verification and administration team have access to pre-SACT toxicity assessments.
M.2	RCNs should facilitate regular meetings with representation from their constituent boards to identify regional shared learning opportunities.
O.1	All boards should continue to support the roll out of the UKONs SACT Passport and competency framework.
O.2	All boards should continue to strengthen documentation of pharmacy training records. The BOPA electronic SACT Verification passport to record competency should be considered for routine adoption across Scotland.
O.3	All boards should ensure that there are systems in place, which provide specific reassurance that medical staff at trainee and specialty doctor level have the appropriate skills, knowledge and training required
O.4	All boards should ensure that there are systems in place which provide specific reassurance that junior medical staff have the appropriate skills, knowledge and training required to assess and manage SACT toxicities, acute oncology presentations and safe handling of SACT principles on commencing a post / rotation within oncology / haematology.
O.5	All boards to ensure that ancillary staff have had clear formalised training and have documentation of this being undertaken.
<b>North Cancer Alliance</b>	
<b>NHS Grampian</b>	
4.3	To ensure appropriate processes are in place to ensure access to SACT Consent forms either on paper or EPR (electronic patient record). These processes should be reviewed, monitored and action plans developed where required.
8.2	Review existing mitigations for intrathecal SACT developed due to the COVID-19 pandemic when board level COVID 19 risk assessments deem this appropriate, to ensure full CEL 21 (2009) compliance.
10.1	To make all efforts to recruit sufficient staff to alleviate workforce pressures and enable allocation of protected learning time for staff undertaking SACT training and SACT competencies.
A.1	To ensure key SACT supportive care resources are easily accessible to all members of the multidisciplinary team across the organisation.

F.2	ARI to ensure compliance with pharmacist verification standards for all prescribed cycles of SACT in ARI, and to provide HIS with evidence of action plan and progress against this action.
<b>NHS Highland</b>	
1.1	To ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for SACT Lead responsible for Highland and Western Isles.
2.3	To develop annual reports that adequately reflect workforce and capacity overview and there is a clear pathway for escalation to appropriate board governance groups.
4.1	To ensure SACT Consent governance and process aligns with the HIS SACT Consent Framework and includes alternative processes for adults with incapacity to ensure consent is in place prior to treatment.
4.3	To ensure appropriate processes are in place to ensure access to SACT Consent forms either on paper or EPR (electronic patient record). These processes should be reviewed, monitored and action plans developed where required.
10.1	To make all efforts to recruit sufficient staff to alleviate workforce pressures and enable allocation of protected learning time for staff undertaking SACT training and SACT competencies.
A.2	To seek support of NCA and other stakeholders to progress reliable IT Infrastructure which supports remote / cross-boundary working.
C.2	To work with NHS Western Isles team to review consent processes and ensure consistent availability of signed consent prior to commencing SACT.
<b>NHS Orkney</b>	
5.3	To review and update SOP for SACT dispensing.
G.1	To confirm that SACT dispensing policies have been reviewed, updated and approved.
<b>NHS Shetland</b>	
5.3	To review and update SOP for SACT dispensing.
<b>NHS Tayside</b>	
1.3	SACT Leads to ensure production of annual SACT reports for review by appropriate board clinical governance group.
4.2	To revise their process for written consent to ensure there is clarity of process and responsibility across all staff groups involved in the process.
4.3	To ensure appropriate processes are in place to ensure access to SACT Consent forms either on paper or EPR (electronic patient record). These processes should be reviewed, monitored and action plans developed where required.
5.1	To update their prescribing policy for medical and non-medical prescribing.

6.3	To provide an update to assure that they have implemented processes to improve sharing of learning from local adverse event reviews.
7.1	To ensure their extravasation guidelines are reviewed, updated, approved and easily accessible to clinical staff.
10.2	To confirm establishment of training processes and logs for all disciplines of staff.
11.1	Should provide assurance that their SOP for SACT delivery out with the cancer centre has formal approval.
A.1	To ensure key SACT supportive care resources are easily accessible to all members of the multidisciplinary team across the organisation.
C.1	To update local SACT Consent SOPs to support the national SACT consent process.
G.1	To confirm that SACT dispensing policies have been reviewed, updated and approved.
I.1	To confirm that the SOP for SACT delivery out with the cancer centre is approved via appropriate governance group.
J.1	To ensure their extravasation guidelines are review, updated, approved and easily accessible to clinical staff.
<b>NHS Western Isles</b>	
2.3	To develop annual reports that adequately reflect workforce and capacity overview and there is a clear pathway for escalation to appropriate board governance groups.
4.3	To ensure appropriate processes are in place to ensure access to SACT Consent forms either on paper or EPR (electronic patient record). These processes should be reviewed, monitored and action plans developed where required.
C.2	To work with NHS Highland SACT team to review consent processes and ensure consistent availability of signed consent prior to commencing SACT.
<b>South East Scotland Cancer Network (SCAN)</b>	
<b>NHS Borders</b>	
5.2	To review and update SACT administration policies, and medical / NMP prescribing policies.
9.1	To ensure robust arrangements are in place for 30-day M&M reviews for haematology patients and ensure that all appropriate personnel and governance groups have access to these at a local and regional level where applicable.
B.1	To ensure processes are in place facilitate clear, unambiguous and timely access to MDT reviews, management plans and advising GP of the treatment plan for all first presentations of cancer across all tumour groups.
B.2	To ensure that there are mechanisms in place to improve access to documentation of changes to SACT prescriptions and treatment decisions.
<b>NHS Dumfries &amp; Galloway – nil specific</b>	

<b>NHS Fife</b>	
1.3	SACT Leads to ensure production of annual SACT reports for review by appropriate board clinical governance group.
6.1	To confirm re-establishment of SACT incident review meetings and to ensure appropriate communication of shared learning locally and regionally.
9.2	To ensure robust arrangements are in place for 30-day M&M reviews for oncology and haematology patients and ensure that all appropriate personnel and governance groups have access to these at a local and regional level where applicable.
H.1	Queen Margaret Hospital and Victoria Hospital to undertake a risk assessment of areas that administer SACT and report back to HIS.
M.1	To confirm that processes are in place to ensure local shared learning of adverse events.
<b>NHS Lothian</b>	
3.3	Given the risks associated with CEPAS / IT failure / downtime NHS Lothian should ensure up to date contingency plans are available and accessible to all disciplines of staff.
7.1	To ensure extravasation guidelines are reviewed, updated, approved and easily accessible to clinical staff.
8.1	Ensure that IT policies are up to date and comply with CEL 21 (2009)
H.1	St John's Hospital to undertake a risk assessment of areas that administer SACT and report back to HIS.
<b>West of Scotland Cancer Network (WoSCAN)</b>	
<b>NHS Ayrshire &amp; Arran</b>	
3.3	Given the risks associated with CEPAS / IT failure / downtime NHS Ayrshire & Arran should ensure up to date contingency plans are available and accessible to all disciplines of staff.
10.3	To develop a process for specialty Dr training and competency assessment.
<b>NHS Forth Valley</b>	
6.2	To provide an update to assure that clinical incident reporting has been embedded into new Forth Valley Governance Structures.
<b>NHS Greater Glasgow &amp; Clyde</b>	
1.2	WoSCAN to ensure appropriate job plans, with adequate time allocated to undertake the role, are in place for SACT Lead in NHS GGC.
F.1	Beatson WoSCC to provide a progress report on compliance to the SACT verification standards (section 4.1) within CEL30 (2012).
N.1	Queen Elizabeth Hospital, NHS GGC to confirm that appropriate actions have been taken to ensure compliance with the full completion of IT SACT prescriptions and ongoing monitoring is in place.
<b>NHS Lanarkshire</b>	

1.2	WoSCAN to ensure appropriate job plans, with adequate time allocated to undertake the role, are in place for SACT Lead in NHS Lanarkshire.
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<b>Managed Service Network for Children &amp; Young People with Cancer</b>	
<b>MSN CYPC Specific Recommendations</b>	
1.8	The MSN CYPC should progress recruitment to a National Lead Pharmacist role to support all boards across the MSN CYPC with progression of SACT related objectives including development of National CEPAS system business case, development of national supportive care guidelines, prescribing practices and SACT governance structures for CYPC services.
3.4	It would be mutually beneficial to formalise the governance processes for supportive care guidelines across the MSN CYPC utilising a phased approach to minimise duplication of effort and aim to develop a 'Once for Scotland' approach across the MSN CYPC. As identified in section 1 a lead pharmacist post-holder could be instrumental in co-ordinating and supporting this process.
6.6	The MSN CYPC should facilitate regular meetings with representation from all boards to identify national shared learning opportunities.
A.3	To ensure shared learning from the site audits from Adults Services, consideration should be given to where guidelines are hosted to ensure they are easily accessible to all members of the multidisciplinary team across the MSN CYPC.
E.2	Provide an update on progress with the national approach to electronic prescribing implementation. In the 2017 National external review it was recommended: '5.8 The Scottish Cancer Taskforce is asked to note that the expert review group strongly endorsed the objective of the Managed Service Network for Children and Young People with Cancer to progress a national approach to the implementation of electronic prescribing of SACT across NHS Scotland as a matter of urgency'. This is particularly impacting on the service in Children's Hospital Dundee, where a paper-based system continues to be used.
M.4	The MSN CYPC should facilitate regular meetings with representation from all boards to identify national shared learning opportunities.
<b>All Boards / Sites</b>	
1.9	All Boards - as recommended in the updated CEL30 (2023 revision) to ensure dedicated time is allocated for Pharmacy and Nursing SACT Leads, to undertake their responsibilities.
H.6	All sites should ensure annual risk assessment undertaken for all areas administering SACT.
H.7	It would be good practice to undertake a risk assessment for areas administering SACT when designing new day case or in-patient areas administering SACT or moving these services to another area.

I.4	All boards across the MSN CYPC should undertake regular auditing and monitoring of the following aspects of safe administration within their SACT Governance Groups to ensure compliance with CEL30 (2012): <ul style="list-style-type: none"> <li>• 2 nurse independent checks</li> <li>• documentation of batch numbers</li> <li>• documentation of expiry dates and</li> <li>• documentation of administration times for both SACT and supportive medications.</li> </ul>
O.7	All boards across the MSN CYPC should support the roll out of the Children's Cancer and Leukaemia Group (CCLG) SACT Passport and competency framework.
O.8	All boards should continue to strengthen documentation of pharmacy training records. The BOPA electronic SACT Verification passport to record competency should be considered for routine adoption across Scotland.
O.9	All boards should ensure that there are systems in place which provide specific reassurance that medical staff at trainee, staff grade and specialty doctor level have the appropriate skills, knowledge and training required.
O.10	All boards should ensure that there are systems in place which provide specific reassurance that junior medical have the appropriate skills, knowledge and training required to assess and manage SACT toxicities, acute oncology presentations and safe handling of SACT principles on commencing a post / rotation within oncology / haematology.
O.11	All boards to ensure that ancillary staff have had clear formalised training and have documentation of this being undertaken.
<b>NHS Grampian</b>	
1.5	To ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for CYPC SACT Lead.
B.3	To ensure a process is developed to consistently ensure MDT discussion is documented and available within the required timeframe
G.2	To confirm systems are in place to record delivery of oral SACT.
K.3	Should have a SOP detailing the required pre-SACT toxicity documentation, this should include: <ul style="list-style-type: none"> <li>• Who can undertake toxicity assessment and what training has been provided.</li> <li>• Where toxicities will be documented for each tumour specific prescribing and administration team, specifying the method of documentation e.g., Toxicity check sheet; clinic letter; FormStream (or equivalent entry) or ChemoCare entry.</li> </ul>
O.6	Should ensure that there are systems and competency assessments in place which provide specific reassurance that junior medical staff have the appropriate skills, knowledge and training required to assess patients' toxicities prior to SACT.
<b>NHS Highland</b>	

1.6	To ensure appropriate job plan, with adequate time allocated to undertake the role, is in place for CYPC SACT Lead.
G.3	To confirm implementation of SOPs for SACT verification and release.
<b>NHS Tayside</b>	
J.1	To ensure their extravasation guidelines are review, updated, approved and easily accessible to clinical staff.
<b>NHS Lothian</b>	
J.1	To ensure their extravasation guidelines are review, updated, approved and easily accessible to clinical staff.
K.3	Should have a SOP detailing the required pre-SACT toxicity documentation, this should include: <ul style="list-style-type: none"> <li>• Who can undertake toxicity assessment and what training has been provided.</li> <li>• Where toxicities will be documented for each tumour specific prescribing and administration team, specifying the method of documentation e.g., Toxicity check sheet; clinic letter; FormStream (or equivalent entry) or ChemoCare entry.</li> </ul>
<b>NHS GGC</b>	
1.7	To progress recruitment of a SACT Lead Clinician with an appropriate job plan and adequate time allocated within their job plan to undertake the role.
I.3	To ensure there are processes in place to facilitate the tracking of individual SACT drugs released from pharmacy.
K.4	To provide assurance that an SOP has been developed to ensure consistency in the documentation of the rationale for SACT dose modifications.

<b>HIS Specific Recommendations</b>	
3.2	HIS and SCN to lead on work to scope out the implementation of a National SACT protocol process to reduce duplication of effort involved with production and maintenance of these.
6.5	HIS to develop a suitable process for national shared learning opportunities from SACT related incidents with regional stakeholders.
H.3	HIS should undertake a review of the Risk Assessment Tool used for Areas Administering SACT.
M.3	HIS alongside regional network stakeholders to explore a process to share learning opportunities from SACT related clinical incidents (outstanding action from 2017).

## Appendix 6: Glossary of Terms

<b>Area Drug and Therapeutics Committee (ADTC) Collaborative</b>	Responsible for advising NHS boards on all aspects of medicines use.
<b>adverse effect</b>	An undesired harmful effect resulting from a medication or other intervention such as surgery.
<b>adverse event</b>	An event that could have caused (a near miss), or did result in, harm to people or groups of people.
<b>aseptic</b>	Free from contamination caused by harmful bacteria, viruses, or other microorganisms; surgically sterile or sterilised.
<b>clinical governance group</b>	Clinical governance is the framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. SACT clinical governance groups within NHS Boards ensure that this true for SACT services.
<b>clinical management guidelines (CMGs) / clinical management pathways</b>	A Clinical Management Guideline (CMG)/Clinical Management Pathway (CMP) (see introduction) is a multi-professional document which promotes multi-professional provision of high quality care by detailing appropriate management through all stages of the patient’s journey – screening, diagnosis, staging, histopathology, investigations, radiotherapy, SACT, supportive treatment and follow up.
<b>Systemic Anti Cancer Therapy (SACT)</b>	Encompasses biological therapies, immunotherapies, advanced therapy medicinal products and cytotoxic chemotherapy.
<b>SACT regimen</b>	The specific treatment course including all SACT drugs, doses, days of administration, treatment intervals and duration of treatment.
<b>clinical trials</b>	A type of research study that tests how well new medical approaches or medicines work. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease.
<b>diagnosis</b>	The process of identifying a disease, such as cancer, from its signs and symptoms.
<b>extravasation</b>	The inappropriate or accidental leakage of an intravenous medicine from the vein into surrounding tissues.
<b>Managed Service Network for Children and Young People with Cancer (MSN CYPC)</b>	This network aims to attain the best possible outcomes for children, teenagers, and young adults with a diagnosis of cancer in Scotland. It ensures that service delivery and pathways of care are consistent across Scotland, with a focus on delivering safe services as locally as possible.
<b>haematologist</b>	A clinician who diagnoses and clinically manages disorders of the blood and bone marrow.
<b>intrathecal</b>	The route of administration for drugs via an injection into the fluid surrounding the nerves within the spinal canal.

<b>intravenous</b>	The infusion of liquid substances directly into a vein.
<b>morbidity</b>	How much ill health a particular condition causes.
<b>mortality</b>	Either (1) the condition of being subject to death; or (2) the death rate, which reflects the number of deaths per unit of population in any specific regions, age group, disease or other classification, usually expressed as deaths per 1000, or 10,000, or 100,000.
<b>NCA</b>	North Cancer Alliance.
<b>near miss</b>	An incident where the people involved came to no actual harm, but which could have had serious consequences.
<b>neutropenic sepsis</b>	This condition is a medical emergency and occurs most commonly in cancer patients undergoing chemotherapy. Patients will have abnormally low levels of a specific white blood cell called neutrophils, which are needed to help the body fight infection.
<b>oncologist</b>	A medical practitioner qualified to diagnose, assess, treat and manage patients with cancer.
<b>peer review</b>	An evaluation of work by others working in the same field.
<b>performance status</b>	A measure of how well a patient is able to perform ordinary tasks and carry out daily activities (for example World Health Organization (WHO) score of 0=asymptomatic, 4=bedridden).
<b>pharmaceutical verification</b>	A process by which a registered pharmacy professional ensures a prescription is clinically appropriate by reviewing relevant clinical parameters and all medicines being taken by the patient. The purpose is to identify, resolve and prevent medicine-related problems.
<b>Regional Cancer Advisory Groups (RCAGs)</b>	Support and co-ordinate the work of WoSCAN and SCAN.
<b>Regional Cancer Networks (RCNs)</b>	There are three regional cancer networks that facilitate communication and partnership working across their regions in order to promote high standards of cancer care which meets the needs of cancer patients. They also support clinical audit and regional planning of cancer services. These networks are referred to as the North Cancer Alliance (NCA), the South East Scotland Cancer Network (SCAN), and the West of Scotland Cancer Network (WoSCAN).
<b>Scottish Cancer Network (SCN)</b>	NHS National Service Scotland was commissioned by Scottish Government to host and resource the Scottish Cancer Network (SCN). This is a dedicated national resource to support and facilitate a 'Once for Scotland' approach to cancer services which will assist in enabling equitable access to care and treatment across Scotland. The two agreed key functions of the Scottish Cancer Network, delivered through regular engagement with key stakeholders,

	<p>including territorial boards, regional cancer networks and Medical Directors, are to:</p> <ul style="list-style-type: none"> <li>• Develop and operate a system for the production, review, and hosting of National Clinical Management Pathways.</li> <li>• Oversee and drive improvement of existing National Managed Clinical Networks and adopt similar national network approaches for other areas, for example areas with low volume activity that may benefit.</li> </ul>
<b>subcutaneous tissue</b>	Also known as the hypodermis, subcutaneous tissue is the innermost layer of skin. It's made up of fat and connective tissues that contain larger blood vessels and nerves.
<b>SACT protocols</b>	A detailed written set of instructions to guide the care of a patient who is receiving SACT. A treatment plan that includes one or more SACT medicines. It is also often described as a SACT regimen.
<b>SCAN</b>	South East Scotland Cancer Network.
<b>supportive treatment guidelines (STGs)</b>	A set of written guidelines to assist medical professionals involved in the acute care of patients receiving SACT.
<b>tissue</b>	A group or layer of cells that work together to perform a specific function.
<b>toxicity grading system</b>	A system for grading the severity of adverse effects experienced by patients receiving SACT.
<b>WoSCAN</b>	West of Scotland Cancer Network.

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or email [his.contactpublicinvolvement@nhs.scot](mailto:his.contactpublicinvolvement@nhs.scot)

#### Healthcare Improvement Scotland

Edinburgh Office	Glasgow Office
Gyle Square	Delta House
1 South Gyle Crescent	50 West Nile Street
Edinburgh	Glasgow
EH12 9EB	G1 2NP
0131 623 4300	0141 225 6999
<a href="http://www.healthcareimprovementscotland.org">www.healthcareimprovementscotland.org</a>	