General principles to support Systemic Anti-Cancer Therapy aseptic capacity pressures

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Contents

Introduction

Demands on Systemic Anti-Cancer Therapy (SACT) services in the UK are increasing with an average of 5-6 per cent growth in SACT treatments per annum[1]. At the same time, there is a growing group of patients living with advanced cancer on maintenance therapies. New treatments of greater complexity which require additional time to prepare and deliver are further increasing demand and challenging capacity. With more than fifty cancer drugs being assessed by the National Institute for Health and Care Excellence (NICE) in the coming twelve months[2], more SACT treatments/indications will inevitably be approved. This is excellent news for patients but puts pressure on the oncology workforce and resources needed.

The UK SACT Board recognises these pressures are not just within the provision of aseptic services but this aspect of SACT provision has been recognised to be severely challenged at a national level. NHS England (NHS-E) and the Medicines and Healthcare products Regulatory Agency (MHRA) are working together to facilitate collaboration at a wider level, with proposals to:

- share aseptic capacity in preparing SACT medicines in a more efficient way to utilise products and staff effectively.
- support preparation of defined SACT by non-nursing staff on SACT day units. Non-nursing staff could include pharmacy technicians and pharmacy assistants and utilisation of closed system devices may help to facilitate this further. Existing regulations and guidance would need to be used as a framework of enablement for this to occur.

The UK SACT Board has been asked to support the development of general principles for managing local services for consideration at organisational level across the UK.

The principles outlined below are to support and release pressure in current SACT services across medical, nursing and pharmacy areas as short-term measures/quick wins. It is recommended that these principles are reviewed by all organisations that supply a SACT service to patients. This includes the NHS, private healthcare and homecare across the whole of the UK.

Note: all principles stated below are for guidance only and each organisation will need to assess each area and the impact within their services individually. It is important to note that these principles should not reduce the efficacy of SACT treatment, affect patient outcomes or reduce patient and staff safety in any way.

The aseptic preparation of a medicine is at the end of a complex SACT pathway, prior to administration. This pathway should be owned by the multi-disciplinary team, ensuring all stages are efficiently optimised.

The key principles set out below are designed to help reduce waste in resources, medicines and time through:

- better utilisation of optimal scheduling
- pre-prescribing SACT
- timely authorisation of treatment
- timely blood reporting in advance where possible and where appropriate
- effective communication around dose changes, delays and missed appointments.

It is possible that a loss of aseptic capacity could be sudden, without sufficient warning to review every patient in response. Services should record this as a possible risk and should consider mitigating this by using a clinical prioritisation framework for all patients so that, in an emergency, decisions about prioritisation could be made quickly.

[1] National Disease Registration Service. SACT Dataset: https://digital.nhs.uk/ndrs/data/data-sets/sact. (Last accessed: September 2023)

[2] National Institute for Health and Care Excellence, Guidance, NICE advice and quality standards in development: https://www.nice.org.uk/guidance/indevelopment. (Last accessed: September 2023)

This document is set out in sections relevant to the three key professional groups involved in the provision of SACT services but should be viewed as a single document supporting a multi-professional approach.

Section One: Advice for Cancer Pharmacy Teams

Background:

- Advanced roles of cancer pharmacists (for example, prescribing in SACT clinics) are at risk due to organisations pulling pharmacy staff back into medicine supply roles (aseptics/dispensary).
- There is a shortage of cancer pharmacists and pharmacy technicians. Retention and recruitment are important for the future of services.
- Experience and training of cancer pharmacy staff is extensive. The British Oncology Pharmacy Association (BOPA) Verification Passport can be adopted by organisations to reduce re-training pressures when staff move.
- Dose banding is well established in the majority of organisations.
- Many organisations have downsized aseptics capacity over the last 15 years due to cost pressures, increasing regulatory requirements for in-house compounding and the increased availability of external outsourcing.
- SACT electronic prescribing and administration (ePMA) systems are well established in most organisations. Changes to existing regimens and new regimens will lead to increased time pressures for cancer pharmacists and those involved in checking protocol writing and set-up (this can include doctors and nurses as well as pharmacy staff). This time pressure will need to be assessed and costs identified.
- Processes within an organisation may state a specific volume of fluid for a medicine to be administered in. This prevents the nurse administering the medicine in a different volume to that stated in the prescription/organisational process. Where a range of volumes can be safely used and administered, and the organisation processes do not allow this administration within current practices, this leads to unnecessary waste and additional aseptic work.
- There is a variation in operational polices for the re-use of SACT products, causing wastage. Some organisations do not allow the repurposing of SACT to alternative patients where this is clinically safe.
- Access to SACT medicines prior to public body approval is occasionally available via pharma-led expanded access and Free of Charge (FOC) schemes. However, no additional service costs are provided by the pharmaceutical manufacturers. This is affecting capacity in aseptic units. BOPA has published a position statement on this issue.

Suggested short-term service modifications (note: some of these points may have already been implemented in some organisations):

Clinical teams responsible for SACT services should:

- Review and consider adopting NHS-E national dose banding for appropriate SACT. The Scottish Oncology Pharmacy Practice Group (SOPPG) has issued dose banded guidelines for Scotland which consider and include NHS-E bands as appropriate. The most up-to-date version of these are held on Regional Network Intranet sites.
  - ***ePMA system change will be needed***
- Consider using ready-made licensed products to support capacity management. This may require changes to ePMA systems where volumes or dose bands do not align.
  - ***ePMA system change will be needed***
- Consider how the pharmacy workforce could work differently – for example, pharmacy technicians to help with pre-verification of prescriptions to facilitate pre-ordering and stock control, and to support nurses in ward-level reconstitution of certain SACT.

- Review SACT regimens used in the organisation and ensure that oral or sub-cutaneous (SC) products are used in preference to those needing aseptic preparation where there is a choice of regimens and it is clinically appropriate.
- Ensure that immunotherapy regimens are given with the longest administration interval (without reducing efficacy) - for example, move to 4-weekly or 6-weekly dosing which will reduce demand.
- Ensure that lower risk products for co-administration alongside SACT (for example, folinic acid, mesna and hydration fluids) are not prepared unnecessarily in pharmacy aseptic units. These items can be prepared in clinical areas by nursing and pharmacy staff but this will increase the workload of nursing and pharmacy teams.
- Ensure ready-made licensed products are used in preference to aseptically-compounded products - for example, there are a range of licensed products available (e.g. irinotecan and gemcitabine). It is strongly recommended that ready-made products are used in preference to purchasing these drugs from commercial compounding companies or preparing them in local aseptic units.
- In order to optimise capacity of commercial compounding companies, review the product range purchased to:
    - prioritise ordering of dose banded and fixed dose SACT that is batch-prepared rather than patient-specific dosing
    - cease ordering less hazardous products (including non-cancer drugs) that can be prepared at ward level – for example, review all monoclonal antibodies (mAbs) (including infliximab in rheumatology) to prioritise ordering of SACT and hazardous products. This would need to be following discussion with nursing colleagues in related specialities.
- Consider introducing ward/day unit-level preparation of non-cytotoxic SACT products usually produced locally – for example, mAbs - particularly those with a fixed dose that are supplied in a single container. Some providers have moved preparation of selected mAbs to ward level - for example, atezolizumab, nivolumab, pembrolizumab, pertuzumab, rituximab and trastuzumab. This option would increase workload for nurses and should only be considered once all other options to reduce demand on aseptic facilities have been explored. Implementation must be with the clear agreement of nursing teams, a risk assessment and use of innovative solutions such as closed-system devices and/or pharmacy staff support at ward level. Organisations that have adopted these practices are encouraged to share their learning with their local pharmacy and nursing networks.
- Where there is a safe dilution volume range associated with a SACT agent, state that range within the SACT protocol. If the volume being delivered differs from the volume stated on the prescription, then the prescription must be changed before administration takes place. By following this process, the drug can then be administered without the need for it to be remade.

    ➢ ***ePMA system change may be needed***

- Optimise organisational policies related to repurposing of SACT, to support reduction in waste. This will enable the return of SACT to pharmacy from day units to be re-used when a drug has not been administered. This must follow robust quality assurance procedures to ensure the safety of the SACT to be re-used.
- Review where ready-made licensed products are labelled and released within pharmacy. Labelling and realising of these ready-made products can take place outside of aseptics but an understanding of process flows within pharmacy and resource utilisation is needed to assess where this process is best undertaken.
- Review where batch-made aseptic-prepared products are labelled and released. This may occur outside of aseptics (ie. review the need for patient labels on inner bags within governance committees). Again, an understanding of process flows within pharmacy and resource utilisation is needed to assess where this process is best undertaken.

- Ensure SACT prescribing systems are rapidly updated to facilitate any changes needed in prescribing or product selection.
  - ***ePMA system change will be needed***
- Ensure prioritisation of SACT approved by national bodies (NICE, NHS-E, Scottish Medicines Consortium (SMC), All Wales Medicines Strategy Group (AWMSG)) over SACT available through pharma-led expanded access and FOC schemes where aseptic capacity is limited.
- Ensure prioritisation of MHRA-approved (or Healthcare Improvement Scotland (HIS)-endorsed in NHS Scotland) expanded access schemes over pharma-led expanded access and FOC schemes where aseptic capacity is limited.

To support the recommendations outlined above, organisations are advised to:

- Seek advice from local pharmacy procurement leads to facilitate off-contract procurement from alternative suppliers of outsourced products if required.
- Develop risk assessments and processes to support safe preparation of lower risk products near to patient environments in collaboration with nursing colleagues.
- Use the BOPA forums to share local solutions that support reducing demands of SACT preparation – for example, procedures for ward preparation of mAbs.
- In England, consider using the NHS-E Cancer Drugs Fund (CDF) community platform on the NHS Futures website as a forum for sharing best practice. *Please note: this site requires prior registration.*
- In Scotland, consider opportunities to discuss product specification or additional products for consideration in National Contract arrangements with the National Procurement Team.
- In Scotland, consider opportunities for collaboration and discussion between the SOPPG and Aseptic Services Special Interest Group to optimise workflow.

Section Two: Advice for Nursing Teams

Background:

- SACT nurses are highly trained and competency must be achieved in all UK healthcare organisations through the UK Oncology Nursing Society (UKONS) SACT Competency Passport which will be linked to the Aspirant Cancer Career and Education Development Programme (ACCEnD) Digitalised career and competency framework.
- The SACT nurse role entails managing and delivering clinical care with increasing workloads and more complex treatments, whilst also training new nurses. Nurses also provide essential education and support to help patients to manage their treatments (for example, oral medicines, peripherally inserted central catheter (PICC) line care, symptom management and reporting).
- SACT nursing recruitment and retention is challenging due to a national shortage and high rates of turnover.
- Increasing drug-preparation and delivery-related activities can result in a more technical focus whilst reducing time and resilience to deliver essential holistic care or to develop innovative practice.
- Nursing role extension to support preparation of drugs such as mAbs must only be implemented after considering the impact this may have on direct patient care and after all other options have been considered.
- Nurse preparation of agents such as mAbs which are not known to have mutagenic, carcinogenic or teratogenic effects, is not a long-term solution for addressing the crisis in aseptics provision and adds to existing workforce challenges in the SACT nursing workforce. Any decision to include this additional work to the workload and roles of SACT nurses must be accompanied by local agreement with nursing staff involved in SACT service delivery and come with investment in nurse staffing, training, assessment and the provision of designated facilities. There should be ongoing monitoring and assessment of this option as the situation may change.
- Risk assessment, business planning, workforce modelling and benchmarking must be undertaken to ensure any new roles are sustainable and do not negatively impact on recruitment and retention of SACT nurses or important work in complex drug management, supportive care and training of new SACT nurses. Where the implementation of extended roles to support drug preparation in clinical areas has a high likelihood of negatively impacting service delivery, staff training and retention or patient safety, alternative approaches to reducing demand on the aseptic unit must be found.

Suggested short-term service modifications:

Clinical teams responsible for SACT services should:

- Ensure sterility of the medicinal product. All cytotoxic drugs must be prepared in aseptic units due to the risk of occupational exposure. Specifically agreed non-cytotoxic drugs can be considered for preparation by nursing or pharmacy staff out of aseptic units at ward/day unit level. This may include mAbs.
- Ensure that all options to reduce demand on the aseptic service have been considered and/or implemented ahead of assessing potential for ward/day unit level preparation of selected SACT products.
- Undertake a full risk assessment if preparation of appropriate SACT (see above) such as mAbs by nursing staff is being considered. The risk assessment should include:
    - Assessment of capacity to prepare appropriate SACT infusions (see above) at ward/day unit level. This work could be independent of, or in collaboration with, pharmacy technicians.

    - Undertake a review of the environment and consider if there is an area suitable for preparation of drugs with appropriate work surface, ventilation, lighting that is free from disruption. Guidance is available from the Specialised Pharmacy Service and NHS England.
    - Use closed-system transfer devices and personal protective equipment (PPE) including gloves, eye protection, apron and face mask when preparing mAbs outside an aseptic unit.
- Prioritise nurse preparation to flat-dose mAbs such as pembrolizumab, nivolumab or atezolizumab, to reduce the need for complex drug calculations.
- Undertake an individual risk assessment of each drug to confirm suitability for nurse preparation prior to moving any mAbs to preparation in a clinical area.
- Ensure clear policies/standard operating procedures are accompanied by staff training before changes to drug preparation are implemented.

Section Three: Advice for Prescribers

Background:

- Consultants and trainees in Clinical Oncology, Medical Oncology and haematology are the predominant prescribers of SACT. There is a well-documented national shortage of clinical oncologists and medical oncologists[3]. Training numbers for these two specialties have increased since 2021 but it will be at least five years before these additional trainees are accredited as consultants and the benefit is seen in oncology services.
- There has been a steady increase in SACT non-medical prescribers from pharmacy and nursing professional groups. This is an excellent career development opportunity and helps retention of key staff. However, this can displace the workforce issues from oncology, pharmacy and nursing, creating vacancies elsewhere.
- Oncology is a research-active specialty. Clinical trials involving Investigational Medicinal Products and early access schemes are available at many centres. All aspects of the SACT patient pathway are more complex in the context of a clinical trial or early access schemes. Similarly, pharma-led expanded access and FOC schemes require additional NHS resource.

Suggested short-term service modifications:

Clinical teams responsible for SACT services should:

- Consider implementing immunotherapy regimens with less frequent attendances as long as this does not reduce efficacy – for example, 6-weekly pembrolizumab.
- Switch from intravenous to oral or SC preparations where this is clinically appropriate.
- Utilise patient self-administration processes in collaboration with pharmacy and nursing teams.
- Consider utilisation of homecare opportunities where available. This could free-up nurse capacity within the organisation. This needs to be in collaboration with pharmacy and nursing teams.
- Consider standardisation where possible to reduce waste – for example, standardised dosing and volumes.
- Adopt national standards as they emerge for consistency, such as dose banding and dose standardisation within England and SOPPG dose bands in Scotland.
- Ensure local protocols include a timeline (for example, 48 hours) for dose and regimen changes, delays to treatment and cancellations to be communicated to the nursing and pharmacy teams.
- Where possible and appropriate, ensure SACT is pre-prescribed one cycle ahead to support aseptic/SACT unit planning.
- Ensure that SACT approved by commissioning bodies is prioritised over SACT available through pharma-led expanded access and FOC schemes where aseptic capacity is limited.
- Have access and oversight of metrics relating to demand and capacity, and use these to inform service transformation.

[3] The Royal College of Radiologists. Clinical Oncology Workforce Census 2022: https://www.rcr.ac.uk/clinical-oncology/rcr-clinical-oncology-workforce-census-2022. (Last accessed: September 2023)

Acknowledgements

About the UK SACT Board

The UK SACT Board is a multi-professional body which provides guidance, oversight and support for the continuing development of SACT services in the UK. Its core membership comprises representatives of the Association of Cancer Physicians, The Royal College of Radiologists (RCR), the Royal College of Physicians, the Royal College of Pathologists, the British Oncology Pharmacy Association and the UK Oncology Nursing Society (UKONS). The Board also has representation from the four UK nations and from other organisations closely involved in SACT services.

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Disclaimer

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