

NCCP Parenteral SACT

Capacity Planning Toolkit

User Manual

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1 Introduction

A working group was convened by the NCCP in 2016 to progress the development of a standardised capacity planning tool for parenteral SACT compounding and dispensing in hospital pharmacy departments in line with recommendation 17 of the NCCP Oncology Medication and Safety Review Report recommendation (1). The tool developed will allow hospitals to assess current demand and plan for future requirements. The facility for local adjustment means that the output of this tool will not be standardised and will not facilitate national bench marking.

The NCCP parenteral SACT capacity planning implementation document should be read in conjunction with this user manual.

The factors considered in the assessment of capacity in this toolkit are:

1. Facilities available
2. Staff available for compounding / dispensing activities
3. Available hours of facilities and staff
4. Isolators / Equipment available
5. Workload
 - a. Standard Time functions
 - b. Fixed Time for non-compounding functions
 - c. Fixed Time for compounding functions
6. Total time for dispensed items

2 Instructions for use of the Capacity Planning Tool

The capacity planning tool is based on an excel format. It is intended for retrospective use although it can be used prospectively if you have the required information. The tool will allow the production of a monthly capacity plan following completion of the toolkit with the details as outlined in the instructions.

The capacity planning tool comprises a number of excel pages to be completed. A certain amount of information is required to be inputted in order to allow it to calculate the capacity as a percentage of the staff and of the isolators. This should be entered as detailed in the instructions page of the spreadsheet. It is recommended to save the entire capacity planning toolkit for each month's calculations individually in order to track the changes in capacity over time and for trend analysis. For monthly updates, use the previous month's spreadsheet, updating the areas required and saving it with the new month and year.

The user manual is laid out in sections, each section refers to the relevant excel page of the capacity planning tool.

2.1 Facilities

Facilities available for parenteral SACT compounding are detailed here. This section is applicable to all hospitals with an aseptic compounding unit (ACU) or stand alone isolator(s). This enables recording of the facilities as they relate to your site. The details should be entered when configuring the capacity planning tool and revised as necessary following any change to opening hours, facilities or staffing. The details entered here do not form part of the capacity calculation.

- Opening Hours
 - Detail days and hours of opening
- Current Facilities and Staffing
 - Facilities:

The number of rooms and the grade at which each room operates should be listed here as appropriate to the unit for which the plan is being completed. The equipment type (e.g. isolators) and the number of each type per room should also be included.

- Staffing within Aseptic Unit

Detail the staff assigned to the service, in Whole Time Equivalent, as per their title, grade and a brief outline of their duties. Only staff time that is assigned to duties in the aseptic unit should be included. Staff time spent on other duties such as ward based activities, MDM attendance, treatment protocol development, clinical check of prescriptions, clinical trial initiation and clinical trial documentation should not be included in the WTE for the aseptic unit.

1. Support workers such as cleaners should be included as the plan can capture if adequate cleaner's time is allocated to the unit to complete the cleaning as indicated.
2. Staff, such as portering staff or other staff involved in the support of services to the aseptic unit are not included in this tool.

2.2 Available hours (Staff and Isolators)

This allows for the available hours for the staff and equipment available for parenteral SACT compounding and dispensing to be calculated. The available hours of work for each staff member and for each isolator should be detailed here numerically. This should be updated each time the capacity plan tool is completed, reflecting the working hours, on a daily basis, of the staff and the number of operating hours of the isolators.

2.2.1 Staff

- Staff should be detailed as per their title and grade along with a brief description of the duties e.g. quality control pharmacist, daily operational senior technician. Each staff member is listed separately to allow for the available hours for that person to be accounted for in the total available staff hours.

Please complete the number of hours for each of the following member of staff

- Pharmacist (per staff member, detailing grade)
- Technician (per staff member, detailing grade)
- Support Worker e.g. cleaner (per person)

Please contact us if you have more staff than allowed for in the current toolkit. This may be done by emailing us at oncologydrugs@cancercontrol.ie.

- Only staff time that is assigned to aseptic unit duties such as compounding and dispensing activities as well as the non-compounding activities essential to the running of an aseptic unit should be included here, as stated previously. E.g. if a pharmacist is based in the aseptic unit but spends 0.2 WTE on clinical duties, the allocation in the capacity plan tool for that staff member is 0.8 WTE.
- Staff in training should be assigned a percentage capability to allow for staff with different levels of training and experience of working in the aseptic unit or with other compounding duties(2). Depending on the local training processes, staff should be allocated WTE equivalent to their stage of training. E.g. for a 4 month training programme, staff should be allocated as follows:

Month of training	Percentage capability	WTE to be assigned
1	25	0.25
2	50	0.5
3	75	0.75
4	100	1

At the end of this training period, staff competency would be assessed. Once a staff member is deemed competent, the WTE should be assigned as for a fully trained staff member.

- Annual leave/ Sick leave should be incorporated here and is reflected by completing the relevant number of hours in the Annual leave/ Sick leave section for that staff member for the applicable period.

- Bank holidays will be reflected here as the number of working days per month is used to calculate the number of staff hours available.

2.2.2 Isolators

- Each isolator is listed individually to allow for variables to be accounted for in calculating the isolator's available compounding time.
- The capacity plan allows for downtime and unavailability of facilities due to planned or unplanned downtimes to be included.

Please complete the details for each of the following

- Isolator, each should have a unique identifier e.g. Isolator A
- Number of work areas per isolator (Usually a 4 glove has 2 work areas, a 2 glove has 1 work area)
- Number of sessions/day
- Duration of each work session *excluding* times taken for isolator cleandown , glove changes and environmental monitoring.
- Number of days per week for which that isolator is ordinarily in operation. Once inputted, this will allow the total number of available hours per day/ week/ month to be calculated)
- The number of working days per month
- Downtime per month. This allows for necessary functions to be accounted for in the total number of available hours per month. These may include:
 - Maintenance and equipment servicing
 - Sleeve changes
 - Quality control (QC) processes such as sessional broth testing, air sampling and particle counting
 - Unplanned breakdown
 - Any other process resulting in decreased availability of isolator for compounding.

2.3 Standard Time Functions

Standard time functions account for the time required to carry out functions that relate both directly and indirectly to the compounding of a product.

The allocation of standard time functions allows for ancillary tasks which are essential to the daily efficient running of an ACU or isolator to be accounted for in the capacity plan. Standard time functions can be segregated into

1. Fixed time for non-compounding functions and
2. Fixed time for compounding functions.

NOTE: The times allocated are intended to reflect uninterrupted time to complete the process indicated. While it is accepted that interruptions and delays commonly occur, the capacity plan is intended to apply to the service when running at optimum efficiency.

2.3.1 Fixed Time for Non-compounding functions

Fixed time for non-compounding functions are functions which are carried out by all staff members that are essential to the safe and efficient running of an aseptic unit and need to be carried out irrespective of the number of items to be compounded.

Quality management (QM) system activities form a large part of these standard time functions and are included here in order to capture the time required for tasks that are essential to the day to day running of an aseptic unit. QM activities are essential to the safe running of any aseptic compounding unit and should account for up to 20% of staff time depending on local facilities and processes involved in the maintenance of those facilities (3). Protected time should be given to staff in order to carry out quality management activities.

1. A list of suggested functions is detailed in appendix 1
2. The total number of hours spent per month on each of the activities relevant to local practice should be detailed as per the category of staff member that is responsible for completing that activity. The capacity planning tool automatically totals the time and subtracts it from the available time per staff type and grade to

allow calculation of the actual time that staff have available for direct compounding activities.

3. Suggested times are included, these have been based on a consensus from the working group and are intended as an example only. These times will vary by Aseptic Compounding Unit (ACU) as they will be dependent on such factors as number of isolators and operators, expiry dates being assigned, activity levels, numbers of sessions etc.
4. ***Sites should amend these times to reflect their local practice.***
5. There are spaces to allow for sites to add other functions where they feel there is a function carried out by their unit that is not detailed in the list of activities. Please ensure to only include activities associated with the ACU (clinical activities including clinical verification of prescriptions should not be included here). This allows for a certain amount of flexibility in the capacity planning toolkit. These spaces may be used to include time spent on functions such as:
 - a. Compassionate use/ Expanded access program drug management where carried out by ACU staff
 - b. Outsource order generation of dose banded/ patient specific products
 - c. Outsource order reconciliation of dose banded/ patient specific products
 - d. Other functions relating to the supply of SACT from the pharmacy where carried out by ACU staff
6. Due to this flexibility, it should be considered that where standard times have been locally assigned and adjusted from the example supplied, there will be differences in the resulting staffing capacity calculated by units including similar sized units with similar staffing levels. This should be flagged in any report using the capacity limits calculated by the tool.

2.4 Total time for Compounded Items

The times taken in the compounding of items both directly and indirectly are accounted for here. It details the following functions:

- Fixed time for compounded items (minutes)
- Average manipulation time for each compounded product (including volume check)
- Total time for product preparation (fixed time plus manipulation time).

These are detailed further below.

2.4.1 Fixed time for Compounded Items (minutes)

Compounding functions involve many more steps than just the compounding production of products. The time taken to process a prescription from receipt to compounding needs to be included and is independent of the complexity of the product. These fixed times for compounding functions allocated in the capacity planning tool allow for the time taken on these compounding activities to be accounted for. This includes all the functions required in the process surrounding compounding:

- Prescription check (non-clinical i.e. technical check of products required)
 - Worksheet/label generation and double check
 - Tray setup and worksheet completion
 - Tray check and worksheet sign-off
 - Transfer process (single spray/ double spray)
 - Volume check (in-process)
 - Labelling post compounding
 - Final check and product release
 - Outsource compounding ordering time is also accounted for here.
- ***Times are fixed for each function***, the time allocated has been agreed following a period of consultation with all hospitals. Although these functions may be segregated and/or named differently, the overall average time should be the same for all sites.
 - The **fixed** time should be assigned to the pharmacist or the technician as fits local policy, skill mix and the availability of accredited checking technicians. Where both pharmacists and technicians may complete the function, divide the time as appropriate –the overall time allocated remains the same i.e. worksheet/ label generation takes 6 minutes which can be assigned to a pharmacist or a technician.

NOTE: All products to be compounded in an isolator are subject to a lockout time (typically 2 minutes) but as functions can be carried on while this is in progress to a variable degree, this time is not included directly but is accounted for indirectly in the standard timings assigned for the transfer process.

2.4.2 Average manipulation time for compounded product (Complexity Bands)

The principle of establishing a complexity band to products manufactured in an aseptic compounding unit has been accepted as a useful means to reflect the variation in time taken to manufacture products due to their inherent complexity (4, 5).

The complexity bands utilised in this tool range from 0 to 5. The higher the band number the more complex a product is to prepare. A list of the most commonly used agents and their associated complexity band is detailed in Appendix 2:.

The allocation of the bands was agreed by the Capacity Planning working group. All hospitals involved in provision of public SACT services will be consulted and the feedback incorporated as appropriate into the final documents and model. See Appendix 1 for detail of complexity band definitions. A list of drugs and assigned bands is detailed in Appendix 3.

- ***Times are fixed for each band.*** Please see Appendix 3: for details on complexity bands.
- Products not currently included can be added to this list by contacting the NCCP at oncologydrugs@cancercontrol.ie, detailing the product type and the manner in which it is prepared as well as whether it is prepared individually or as a batch. The list detailed in Appendix 3 of the NCCP Parenteral SACT Capacity Planning Toolkit User Manual¹ will be maintained by the NCCP. This will be regularly refreshed following requests to include additional products.
- There is nothing here that needs to be completed, this is a fixed field.

2.4.3 Total time for Product Preparation (fixed time plus average manipulation time)

This is a fixed field which calculates automatically once the fixed time for compounded items has been assigned.

This will be used in the calculation of the capacity relative to the number of aseptic unit staff and the number of isolator hours.

¹ Appendix 3: Drugs and Assigned bands

2.5 New month 20XX (Calculation of the Capacity)

Count the number of products for each complexity band for the period for which capacity is being assessed.

- Retrospectively: Complete the number of compounded products in each relevant complexity band to allow for the total time for product preparation to be calculated
- Prospectively: Complete the projected number of compounded products in each relevant complexity band to allow for the total time for product preparation to be calculated.

The plan will calculate the capacity relevant to the number of

- A. Staff expressed in terms of pharmacists
- B. Staff expressed in terms of technicians
- C. Overall staff
- D. Isolators
 - a. Isolators may be expressed as a whole or as individual isolators to allow for sites that segregate products and allocate them to particular isolators. The number of each band for that isolator should be recorded and entered in the section assigned to the isolator.
 - b. The amount of fixed time to be allocated to this isolator should be included as a fraction of time that staff are assigned to this isolator e.g. 0.2 to reflect a 20% allocation to this isolator. This fraction will also be used in calculating the available hours of staff to work in this isolator.

Once the plan has been completed for the period for which capacity is being assessed, record the data and compare to previous months² in order to carry out trend analysis as recommended in section 2. Please see NCCP parenteral SACT capacity planning toolkit implementation document for guidance on capacity limits and capacity limit breached.

² Alternate time periods e.g. 4 weeks may be used as suits local practice to allow for comparability

Appendix 1: Fixed Time for Non-Compounding Functions

Activity	Comment
Managerial Duties - Rotas/reports/ interviewing /etc.	
Quality management activities	
Environmental Monitoring	
Training / Teaching	
Stock Control – management	
Documentation control	e.g. Chemo diaries/ all ACU SOPs
Support room functions	e.g. Dispensing/checking chemo/ support meds/dispatching
Audit and Environmental Audit	
Service development (Local/ Regional)	
Validation tests	e.g. Broth kits /Isolator broth fills/ gowning
Isolator session cleans	
Cleaning equipment /surface cleans/ laundry/ general household	
Dispensing/checking batch products	
Meetings	e.g. Weekly Staff/Quality Assurance
E-mail / written communication	
Waste Management	
Handwashing/ Gowning	
Other	e.g. Drug information queries relating to aseptic unit e.g. suitability of alternate diluents

Appendix 2: Complexity Band Definitions

A Complexity Band is applied to each product manufactured in the aseptic compounding unit as well as all products that have been outsourced as a stock item (i.e. not supplied as a patient specific) or as a patient specific item.

This applies to all compounded preparations that are used in the treatment of cancer whether the drugs involved are cytotoxic or monoclonal antibodies (mAbs).

The timings associated with each complexity band have been based on a consensus from the working group benchmarked to international practice. The times assigned reflect the average time taken by a rotational staff member, trained and deemed competent through local training processes, to complete the manipulation of a number of items within each band.

Each Band is defined below:

A. Band 0

A.1. The unit of issue is provided as a **ready made product** (procured from an outsourced supplier or previously made in-house) e.g. liquid in a pre filled syringe, infusion bag, infusor.

B. Band 1

B.1. The unit of issue is provided as a **liquid in ampoules, vials or a bag** and withdrawn into a syringe for bolus administration e.g. 5-fluorouracil 1000mg in 40ml, epirubicin 90mg in 45ml.

C. Band 2

C.1. The unit of issue is provided as a **liquid in ampoules or vials and required further dilution before administration** e.g. vincristine 2mg in 50ml Sodium Chloride 0.9%, etoposide 220mg in 1000ml Sodium Chloride 0.9%.

C.2. The unit of issue is provided as a **readily soluble powder for reconstitution, in ampoules or vials and withdrawn into a syringe for bolus administration** e.g. Bleomycin 15,000units in 5ml Sodium Chloride 0.9%.

C.3. Any infusion where the **dose is removed from up to 5 vials, and aseptically added to an empty PVC infusion bag of an empty ethyl vinyl acetate (EVA) infusion bag or glass container** e.g. cetuximab 800mg infusion.

D. Band 3

- A. The unit of issue is provided as a **powder/concentrate for reconstitution in ampoules or vials and requires further dilution before infusion**. E.g. bendamustine 140mg in 500ml Sodium Chloride 0.9%.
- B. The unit of issue is provided as a **slowly dissolving powder for reconstitution in ampoules or vials** and withdrawn into a syringe for bolus administration e.g. cyclophosphamide 970mg in 47ml.
- C. The unit of issue consists of **greater than one drug to be provided in a single infusion where each is supplied as a liquid in ampoules or vials** e.g. doxorubicin 24mg in 12mls and vincristine 0.4mg in 0.4ml added to 1000ml Sodium Chloride 0.9%.
- D. The unit of issue is provided as a **concentrate which requires an initial dilution and which requires further dilution before administration** e.g. temsirolimus 25mg in 250ml Sodium Chloride 0.9%.
- E. Any infusion where the **dose is removed more than 5 vials, and aseptically added to an empty PVC infusion bag of an empty ethyl vinyl acetate (EVA) infusion bag or glass container** e.g. Nelarabine infusion.
- F. **All infusor devices which are prepared in aseptic pharmacy facilities with the aid of filling technology.**

E. Band 4

- E.1. The unit of issue consists of **two drugs to be provided in a single infusion where one, or both is, supplied as a powder for reconstitution in ampoules or vials** e.g. Cyclophosphamide/mesna infusion.
- E.2. The unit of issue is provided as a **powder for reconstitution in ampoules or vials requiring more than one diluent to be added in sequence before further dilution prior to administration** e.g. Carmustine 300mg in 500mls Glucose 5%.
- E.3. The unit of issue is provided as a **concentrate or powder which requires a minimum stand time after initial dilution and which requires further dilution**

before administration e.g. cabazitaxel 45mg in 250ml Sodium Chloride 0.9%, nab-paclitaxel 225mg in 45ml.

F. Band 5

- F.1. The unit of issue is provided as a **very slowly dissolving powder/ concentrate for reconstitution in ampoules or vials which require constant aggravation during reconstitution and which require further dilution before administration** e.g. melphalan 250mg in 250ml Sodium Chloride 0.9%.
- F.2. **Any bolus or infusion that requires isolator gloves to be changed after preparation** e.g. Amsacrine infusion.
- F.3. **All infusor devices which are prepared in aseptic pharmacy facilities without the aid of filling technology.**
- F.4. **Any bolus or infusion that requires use of specialist equipment such as water bath or drug eluting beads e.g. Myocet® infusion, DOXOrubicin in DC beads.**

Band 5 is the **maximum band** that can be assigned to a preparation.

Note: Volume withdrawal from infusion bags

If a volume needs to be withdrawn from an infusion bag to facilitate the addition of the chemotherapy drug, this is an additional manipulation and the complexity band assigned should be increased as follows:

If the volume withdrawn is less than or equal to 50mls, then the assigned band should stay the same. If the volume withdrawn is greater than 50mls, then the assigned band should be increased by 1.

Appendix 3: Drugs and assigned bands

Please note this list is not exhaustive. If a drug is not listed below e.g. new products, combination products, compassionate use products or clinical trial products, please contact the NCCP to assign band and include in the next review. Alternately, sites may assign a band as detailed in complexity band definitions.

If the available form of the drug changes due to e.g shortage of supply of a solution product resulting in the need to use a powder for reconstitution, adjust the assigned band accordingly.

All products are compounded in a *bag of diluent for administration as an infusion* unless otherwise stated.

Drug name (6)	Band
Aflibercept	2
Aldesleukin	3
Alemtuzumab	2
Alemtuzumab (SC)	1
Amphotericin	4
Amsacrine	5
Arsenic trioxide	2
Asparaginase IVB/ IM/ SC	2
azaCITIDine SC	3
Azathioprine	3
BCG bladder installation	2
Bendamustine	3
Bevacizumab	2
Bevacizumab (Intravitreal) – batch of up to 20	4
Bevacizumab (Intravitreal) – batch of over 20	5
Bleomycin IVB/ IP	2
Bortezomib	2
Brentuximab vedotin	3
Busulfan	2
Cabazitaxel	4

Drug name (6)	Band
Calcium Folate	2
CARBOplatin	2
Carfilzomib	3
Carmustine	4
Ceftazidime (Intravitreal) – batch of up to 10	4
Ceftazidime (Intravitreal) – batch of over 10	5
Cetuximab	2
CISplatin	2
Cladribine	2
Clofarabine	2
Crisantaspase	2
Cytarabine	2
Cytarabine IVB/ SC/ IT	1
Cyclophosphamide (from readymade solution)	2
Cyclophosphamide IVB	1
Cyclophosphamide (from readymade solution)/ mesna	3
Dacarbazine	3
DACTINomycin	2
Daratumumab	2
DAUNOrubicin (doses \leq 100mg)	4
DAUNOrubicin (doses > 100mg)	5
Decitabine	3
DOCEtaxel	2
DOXOrubicin IVB	1
DOXOrubicin liposomal formulation (Myocet®)	5
DOXOrubicin pegylated liposomal formulation (Caelyx®)	2
DOXOrubicin in Hepaspheres	5
DOXOrubicin in DC beads	5
DOXOrubicin/ vinCRISine	3
DOXOrubicin/ vinCRISine/ etoposide	3
epiRUBicin IVB	1
eriBULin	2
Etoposide	2

Drug name (6)	Band
Fludarabine	3
Fluorouracil IVB	1
Fluorouracil	2
Fluorouracil Infusor	5
Ganciclovir	3
Gemcitabine	2
Idarubicin	2
Ifosfamide	3
Ifosfamide/ mesna	4
Infliximab	2
Interferon Alfa-2a	2
Interferon Alfa-2b	2
Interferon Gamma	2
Ipilimumab	2
Irinotecan	2
Mechlorethamine	3
Melphalan	5
Methotrexate IVB/ SC/IT	1
Methotrexate	2
Mifamurtide	5
mitoMYcin IVB	2
mitoMYcin	3
mitoXANTRONE	2
Nabpaclitaxel	4
Nelarabine	4
Nivolumab	2
Obinutuzumab	2
Ofatumumab	2
Oxaliplatin	2
PACLitaxel	2
Panitumumab	2
Pegaspargase IM/ IVB	2
Pembrolizumab	3

Drug name (6)	Band
PEMEtrexed	3
Pentamidine	3
Pentostatin	3
Pertuzumab	2
Pixantrone	3
Raltitrexed	3
riTUXimab	2
riTUXimab SC	1
Siltuximab	4
Streptozocin	3
Temsirolimus	3
Thiotepa	2
Topotecan	3
Trabectedin	3
Trastuzumab	3
Trastuzumab SC	1
Trastuzumab emtansine	3
vinBLAS ^{tine}	2
vinCRIS ^{tine}	2
Vindesine	2
Vinflunine	2
Vinorelbine	2
<p><i>SC= Subcutaneous</i></p> <p><i>IVB= IV Bolus</i></p> <p><i>IT= Intrathecal</i></p> <p><i>IM= Intramuscular</i></p> <p><i>IP=Intrapleural</i></p>	

3 References

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