NCCP Parenteral SACT

Capacity Planning Toolkit

Implementation Document

Version	Date	Amendment	Approved By
1	07/06/2017	Version 1	Working Group

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Acknowledgements

The NCCP would like to thank the following people for their contribution and assistance in developing and approving the capacity planning tool and associated documents.

- Members of the Working Group
- Ms. Lorraine Mullen, Unit Manager, Altnagelvin ACU, Derry
- Mr John Wheeler, NHSIQ, NHS England
- Ms Gail Povey, Chemotherapy Electronic Prescribing Lead Pharmacist, South West Wales Cancer Centre, ABMU Local Health Board
- Mr Don Wallace, Regional Quality Assurance Specialist Pharmacist, Northern Ireland

1 Background

In 2014 the National Cancer Control Programme published the findings of an Oncology Medication and Safety Review(1) which was conducted across the 26 hospitals in Ireland involved in the administration of systemic anti-cancer therapy (SACT) in adults and children. A key recommendation[1] from this review was to develop: "A capacity-planning model to support hospitals in their local service planning with regard to day ward activity and staffing requirements".

One element of this capacity planning model is the workload associated with the compounding and dispensing of parenteral Systemic Anti-Cancer Therapy (SACT) whether it is compounded locally in a hospital or outsourced to a third party company. Best practice dictates that workload associated with these activities be documented and managed utilising a capacity plan (2). This is required to ensure that:

- Quality and safety standards are not compromised
- Error and defective product rates do not increase as a result of workload
- Response/lead times for locally compounded SACT remain within agreed time limits
- Excessive overtime is not worked or excessive pressure placed on staff (2)

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. This tool 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. This is an initial step towards an overall capacity-planning model as outlined in recommendation 17 of the NCCP Oncology Medication Safety Review.

[1] Recommendation 17

2 Scope and Objectives of the working group

To develop a capacity plan which integrates information on volume and complexity of workload, time and equipment available and the staff and facilities required in the compounding and dispensing of parenteral SACT.

- The capacity plan developed would have the following attributes: It should allow a full understanding of demand and preparation constraints, and appropriate strategies to highlight imbalances in a timely manner to effect appropriate action.
- It should address the entire scope of work undertaken in the aseptic unit including essential day to day tasks such as maintenance of the quality management system.
    - Clinical work carried out by staff in the aseptic unit was considered to be beyond the scope of this document as it will be included in the general Pharmacy Department cancer manpower planning.
- If aseptic unit staff are involved in the ordering and dispensing of outsourced products, this should be included (2).

The terms of reference and membership of the working group are included in Appendices 1 and 2.

3 Methodology

A review of existing capacity plans was carried out in order to identify models that may be suitable. This involved an assessment of the literature as well as analysis of models in use in other hospitals both in Ireland and in the UK.

The working group agreed that the adaptation of the capacity plan in use in Altnagelvin would be suitable for use in an Irish setting.

The model was drafted, agreed and tested in spreadsheet format. An enhanced format may be developed in the future.

A consultation was undertaken following completion of the model. All hospitals involved in provision of public SACT services were consulted prior to the finalisation of the documents and model.

4 Capacity plan design

The compounding of SACT may happen under a number of different circumstances in a hospital:

1. Compounded in a Pharmacy Department
    a) Using closed system transfer devices
    b) In stand-alone isolators / laminar airflow cabinets
    c) In an Aseptic Compounding Unit (ACU)
2. Compounded at ward level - near patient preparation
3. Outsourced
4. A combination of the above

4.1 Factors considered

The capacity plan developed would need to reflect these different options. The main factors considered in the development of the capacity plan were:

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

4.2 Calculation of Capacity

The capacity is determined by using a combination of;

- the fixed time for non-compounding functions,

- the fixed time for compounding functions and
- the locally allocated times for the standard time functions.

Fixed times for compounding functions are assigned a complexity band to account for different complexities associated with the manufacture of a product. The capacity will then be expressed as a means of overall staffing levels or with regard to pharmacist/ technician time as well as with regard to equipment availability. Equipment availability can be expressed as means of overall equipment or split so that certain products can be assigned to particular equipment.

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. A certain amount of flexibility is allowed for in the toolkit as it is recognised that there may be contrasting factors in local sites contributing to poor efficiencies in the compounding and dispensing process.

4.3 Variability in Pharmacy SACT services

It is recognised that there is variability in the operation of units related to many factors including but not limited to; pharmacy size, availability of aseptic unit or other facilities, service demands, staffing and skill mix. Due to the flexible nature of the standard timings to be assigned in the capacity calculations, it allows for local variability in facilities and practice to be reflected in the calculation of capacity. This may lead to differences in the resultant capacity limits calculated even in similar sized units with the same volume of staff.

Any reports including the capacity limits calculated by this toolkit must include the caveat that the output of this toolkit cannot be used in benchmarking as sites have set the standard time functions locally. A realistic baseline, reflective of current practice at each site should be established upon first use of this toolkit to calculate capacity. It is recommended that this is supplied to the line manager for the aseptic unit as a means to

establish baseline. This will give a measure against which to flag future changes in capacity. Advice may be sought from NCCP @ oncologydrugs@cancercontrol.ie if needed.

A separate document is available with details on the operation of the capacity planning tool – see the NCCP Parenteral SACT Capacity Planning Toolkit User Manual. This document details the standard time functions that should be considered, the fixed time function timings and the complexity bands to be assigned.

5 Implementation

5.1 Capacity Plan documents

Each hospital should have a locally approved capacity plan document which details the processes supporting the use of the capacity plan. This should include escalation policy details and contingency plans. The capacity plan document should be reviewed at least annually or when there are significant changes to the unit such as a marked increase in supply or demand. Any changes should be evaluated through the change control system (2, 3).

The capacity plan should be approved locally within hospital management as a means by which pharmacy workload can be assessed. Compliance with the capacity plan should be assessed by inputting the required details into the capacity planning toolkit. The toolkit will allow the production of monthly capacity levels which can be used to capture a baseline and to allow for trend analysis over time.

5.1.1 Capacity Limits

The aseptic unit should aim to work as efficiently as possible within the production hours available. Where the standard time functions are not included, it is recommended that aseptic units operate at 70-80% capacity with regard to staffing in order to allow adequate resource for the associated ancillary tasks including quality management activities.(3) Where the capacity plan includes standard time functions such as quality management activities, it is recommended that aseptic units should aim to work at 90-110% capacity with regard to staffing.(2) As the capacity plan developed by the NCCP allows for essential tasks such as quality management activities to be included, it is recommended that aseptic units should aim to work at 90-110% capacity with regard to staffing[2] (2, 3).

[2] Assumes no isolator capacity ceiling

5.1.2 Breaches to Capacity Limits

Capacity plans can be retrospectively applied to the previous month's activity to assess compliance to the agreed capacity limits. They may also be used prospectively where data is available. If the capacity plan shows breaches of the limits put in place for longer than an agreed period of time e.g. three months, this warrants discussion with pharmacy management as work above the upper limits may mean that time is being taken from the essential non-compounding activities included in the plan. (2)

Where capacity breaches are ongoing and where quality and safety standards run the risk of being compromised, this should be escalated as per the local escalation policy and the appropriate contingency steps put in place. This should be documented on the hospital's risk register until measures are put in place to address the issues.

An agreed escalation policy and contingency plan should be in place to:

- Define the locally agreed capacity breach limits,
- Define the reporting mechanism for such breaches
- Detail the escalation policy
- Manage breaches in agreed capacity limits. e.g. by reducing workload, increasing staff or outsourcing supply such as dose banded products.

5.2 Inclusion of products in use in non-cancer patients

It is acknowledged that some pharmacy aseptic units compound products for use in patients outside of oncology/ haemato-oncology. Where this occurs, units may incorporate these products into the capacity plan in order to represent the capacity of the unit as a whole. These products will be included in Appendix 3 of the NCCP Parenteral SACT Capacity Planning Toolkit User Manual[3] 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

[3] Appendix 3: Drugs and Assigned bands

Capacity Planning Toolkit User Manual[4] will be maintained by the NCCP. This will be regularly refreshed following requests to include additional products.

[4] Appendix 3: Drugs and Assigned bands

6 Use of the Capacity Plan Tool

The use of the capacity plan tool is outlined in the NCCP Parenteral SACT Capacity Planning Toolkit User Manual.

This tool will allow the production of monthly capacity levels following completion of the toolkit with the details as outlined in the instructions. The toolkit requires certain information 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. Following completion of the month's figures, amend the name of the month as appropriate. 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.

6.1 First use of the toolkit (Baseline)

All the details required should be included in order for the capacity plan toolkit to calculate the capacity as a percentage of the staff and the isolator.

6.2 Monthly update of the toolkit (Update monthly)

All the details required to update the plan from the previous month's calculation should be included in order for the capacity plan toolkit to calculate the capacity as a percentage of the staff and the isolator for the month in question. Ensure to save each month separately as outlined above.

All queries and comments should be submitted to oncologydrugs@cancercontrol.ie.

Appendix 1: Capacity Planning Working Group Terms of Reference

Membership:

- NCCP Chief Pharmacist (Chair)
- A minimum of four hospital pharmacists representing both cancer centres and non-cancer centres, with an interest in aseptic compounding unit capacity planning.
- Industry specialist
- Project Manager

Objective

This document outlines the responsibilities of the working group who will oversee the development of a national capacity planning tool for use in Irish hospitals delivering SACT.

The working group will be responsible for:

- Decision making in relation to the capacity markers to be measured
- Decision making and guidance regarding the methodological approach
- Developing the capacity planning model
- Communicating with key stakeholders and pharmacy colleagues about the project
- Agree the final National Capacity Planning Model for pharmacy aseptic compounding units

Frequency of Meetings

The appointment term will be approximately six months, with three to four meetings being held during this time. All meetings can be facilitated by teleconference. The working group may be reconvened from time to time to facilitate refreshing of the documentation

Secretariat

Secretariat will be provided to the group by the NCCP

Appendix 2: Members of the NCCP Capacity Planning Working Group

Chair	Patricia Heckmann, Chief Pharmacist, NCCP
Project manager	AnneMarie De Frein, Pharmacist, NCCP
Industry specialist:	Jackie Donohoe, Baxter Healthcare Limited
Hospital Pharmacist:	Harold Lewis, Chief II Pharmacist, University Hospital Galway
	Olivia Flynn, Chief II Pharmacist, University Hospital Limerick
	Pat O'Dowd, Senior Pharmacist, University Hospital Kerry
	Nuno Silva, Chief II Pharmacist, St. Vincent's Private Hospital
	Eoin Tabb, Pharmacist, University Hospital Waterford
	Ali McPhillips, Pharmacist, Mater Private Hospital
	Lorraine Griffin, Pharmacist, Cork University Hospital

7 References

1. NCCP. NCCP Oncology Medication Safety Review Report. 2014.
2. Society RP. Quality Assurance of Aseptic Preparation Services: Standards Handbook, Part A+B. 5th Edtn.: NHS Pharmaceutical Quality Assurance Committee, Royal Pharmaceutical Society; 2016.
3. MHRA. MHRA Guidance for Specials Manufacturers. 2015(2).