

United Lincolnshire Hospitals  NHS Trust PHARMACY DEPARTMENT STANDARD OPERATING PROCEDURE			
Procedure Title:		<u>Aseptics Capacity Planning and Monitoring</u>	
Reference Number:	ASE/0013	Version:	2.0
Written By:	F. Marin	Approved By:	Pharmacy Governance
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1.0 Purpose

This procedure describes the processes to be followed to ensure the capacity in the aseptic dispensing units is planned and regularly reviewed to guarantee that the level of activity in the unit does not exceed the point above in which quality and safety standards would be compromised.

2.0 Area

This procedure must be followed by all the staff working in the pharmacy aseptic units at United Lincolnshire United Hospitals.

3.0 Duties

All staff are required to read, understand and follow this procedure. Any deviation from the approved procedure must be documented following the process laid down in the deviation procedure.

The Chief Pharmacist must ensure that the units have a current and effectively implemented capacity plan.

4.0 Actions

Capacity is the total output that can be produced safely within existing resources.

Capacity plan is the process of determining the capacity – be it the workforce, equipment or premises- needed by an organisation to meet changing demands for its services or products and using this information to improve efficiency or plan for an impending change.

4.1 Description of the aseptic dispensing activities

The pharmacy dispensing aseptic units operate from Monday to Friday excluding Bank Holidays from 9:00 am till 17:00 pm.

Aseptic dispensing includes:

- Preparation of chemotherapy (cytotoxics and monoclonal antibodies)
- Preparation of other non-chemotherapy cytotoxics and monoclonal antibodies e.g. methotrexate for ectopic pregnancy

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- Preparation of other hazardous medicines, e.g. ganciclovir
- Preparation of neonatal and paediatric total parenteral nutrition
- Preparation of adult total parenteral nutrition
- Preparation of other intravenous products, e.g. intraocular preparations

4.2 Staff available for performing all aseptic preparation and supportive activities

4.2.1 Lincoln Establishment

Pharmacist Band 6/7 X 1 WTE

Specialist Aseptics Pharmacy Technician Band 6 X 1 WTE

Pharmacy Technician Band 5 X 1 WTE

Pharmacy Support Workers Band 3 X 4 WTE

4.2.2 Pilgrim Establishment

Pharmacist Band 6/7 X 1 WTE

Specialist Aseptics Pharmacy Technician Band 6 X 1 WTE

Pharmacy Technician Band 5 X 1 WTE

Pharmacy Support Workers Band 3 X 3.5 WTE

4.3 Capacity Tool

4.3.1 A capacity tool has been developed to plan capacity and record the aseptic activity at Lincoln County Hospital and Pilgrim Hospital.

4.3.2 The capacity tool uses adjusted units. A factor used to account for the varying complexity of different products. The dispensing of aseptic outsourced products is also included in the capacity tool.

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Preparation Timings For Product Categories									
Section 10 Dispensed doses	Worksheets & Labels	set up	set up check	Transfer	Manipulation time	Bagging (including labelling product)	Final Check	Average item time	Units
Cytotoxics									
Simple Cytotoxics (S Cyto)	5	5	7	5	10	3	4	39	39
Complex Cytotoxics (C Cyto)	5	7	9	5	15	3	5	49	49
Intrathecal Chemotherapy (ITC)	5	5	7	5	10	3	5	40	40
Elastomeric Cytotoxics (Pump)	5	5	7	5	15	3	5	45	45
Simple Monoclonals (S Mab)	5	5	7	5	10	3	4	39	39
Complex Monoclonals (C Mab)	5	7	9	5	15	3	5	49	49
Pre-filled Product	5	0	0	0	0	3	2	10	10
CIVAS									
Infusion bags (Civas B)	5	5	7	5	10	3	4	39	39
Syringes (Civas S)	5	5	5	5	10	3	4	37	37
Eye Drops (Eye D)	5	5	5	5	10	3	4	37	37
Eye Injections (Eye I)	5	5	5	5	10	3	4	37	37
Pre-filled Product	5	0	0	0	0	3	2	10	10
TPN									
Adult TPN	7	5	5	5	10	3	5	40	40
Neonatal TPN simple (Neon TPN S)	10	5	5	5	10	3	7	45	45
Neonatal TPN complex (Neo TPN C)	10	15	10	10	45	3	15	108	108
Pre-filled Product Adult	5	0	0	0	0	3	7	15	15
Total									

- 4.3.3 All aspects of the unit workload are covered in the capacity tool (e.g. maintenance of the Pharmaceutical Quality Systems), not just the preparation of the products. A fixed time per session is included in the capacity tool for the preparation of the isolators and environmental monitoring and a fix time per item manufactured is also included for the preparation of the worksheets, labels, transfer and release.
- 4.3.4 Other non-production activities, e.g. training, human resources issues and meetings are also considered in the capacity tool.

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Activity	Hours Per Week						
	ATO Band 2	ATO Band 3	Technician Band 4	Technician Band 5	Technician Band 6	Pharmacist Band 7	Accountable Pharmacist
Meetings	0	0.5	0.5	0.5	2	0.5	
Clinical Time	0	0	0	0	0	0	
Quality Management e.g Worksheets, SOP's, Investigations, CAPA..	0	0	0	0	15	0	
Validation/Broth kits	0	0.5	0.5	0.5	0.5	0	
Ordering							
	0	1	1	0	0	0	
Cleaning the units/general house keeping	0	8	8	0	0	0	
Delivering Teaching/training	0	0.5	0.5	0.5	3	2	
Problem Solving/Service Development e.g queries, looking for charts, items, stability etc	0	1	2	3	5	2	
Human Resource Issues including PADR's, sickness.	0	0	0	0	1		
Finance reports e.g private pts, information requests	0	1	0	1	0.5	0	
Annual leave/Bank Holidays/Sickness							
Weekly Total	0	12.5	12.5	5.5	27	4.5	
Monthly Total (weekly x 4.3)	0	53.75	53.75	23.65	116.1	19.35	

4.4 Recording of Activity/Capacity

- 4.4.1 The capacity tool is used to log the workload of the units daily and weighted workload figures are then plotted graphically and interpolated against the assigned capacity.
- 4.4.2 The workload coordinator must record the workload figures in the capacity tool at the end of the day.
- 4.4.3 The workload figures are obtained from Ascribe (Ascribe Capacity Plan Report).

4.5 Monitoring of activity

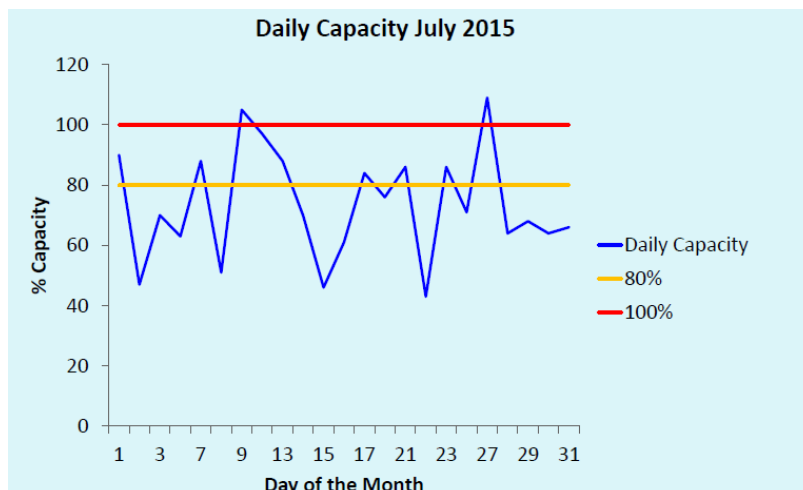
- 4.5.1 Activity must be reviewed and monitored **monthly** by the Aseptic Group and earlier if capacity issues or concerns are highlighted. **A deviation will be completed in a timely manner when excursions occur** and the Senior Pharmacy Management Group must be informed.

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Day	Daily Capacity %	Day	Daily Capacity %
1	90	17	84
2	47	18	76
3	70	19	76
4	70	20	76
5	70	21	86
6	63	22	43
7	88	23	86
8	23	24	71
9	108	25	71
10	97	26	100
11	70	27	100
12	70	28	64
13	88	29	64
14	70	30	64
15	45	31	66
16	63		

Capacity July 2015 72%



4.5.2 The capacity plan and trends must be reviewed annually by the Senior Pharmacy Management Group and staff establishment adjusted if required.

4.5.3 Any changes in capacity should be evaluated through the change control system.

4.6 Management of excursions

4.6.1 A deviation must be completed on a timely manner following excursions and reported to the Senior Management Group. Capacity should only be exceeded infrequently.

4.6.2 Occasional peaks in workload or staff shortages will normally be managed:

- by redeploying staff from other non-essential duties to help with the work or to release other staff to undertake the work. Assistance can also be called from the sister unit if they have the capacity to help.

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- maximising the use of outsourced products to release time etc, for high risk preparations to be made in pharmacy. High risk products:
 - Cytotoxics
 - Neonatal Parenteral Nutrition
 - Additions to Adult Parenteral Nutrition
 - a plain Adult Parenteral Nutrition bag will be dispensed and any required extra electrolytes should be reconstituted and given separately in the clinical area. Cytotoxics and Neonatal Parenteral Nutrition will take priority over Adult Parenteral Nutrition.
 - lower risk products to be made up on the wards and not in pharmacy aseptics. Lower risk products:-
 - CIVAS
 - Intraocular Injections- follow Trust policy for preparation of antibiotics for endophthalmitis
- 4.6.3 Contingency plans exist to manage various scenarios and should be followed in the short term whilst a more controlled mechanism of action can be formulated. See recommissioning and contingency plan procedure.
- 4.6.4 Long term trends showing increased or decreased capacity need to be appropriately reviewed, documented and actioned by the Pharmacy Senior Management Group.

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