NCCP DOSE BANDING IMPLEMENTATION AND FAQ DOCUMENT FOR SYSTEMIC ANTI-CANCER THERAPY (SACT)

Version	Date	Amendment	Approved By
1	03/06/16	Version 1	Working Group
2	23/08/19	Version 2: Update of section 3 FAQ regarding NCIS	Working Group
3	01/03/22	Version 3: • Inclusion of details of Covid-19 Dose Banding Tables • Amendment of FAQ 3.16 regarding NCIS • Changed to Tall Man lettering	NCCP
4	31/12/24	Version 4: Update to: • Sections 1, 2.4, 2.5, 2.6, 3.9 • Section 3.3, 3.6, 3.7 – minor readability changes • Section 3.13 to clarify cyclophosphamide IV Infusion • Added Tall man lettering for cycloPHOSphosphamide	NCCP

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1 Background

This document is intended for use in conjunction with the NCCP Guidance document on Dose Banding and the NCCP Dose Banding Tables. The use of Systemic Anti-Cancer Therapy (SACT) has risen significantly in recent years resulting in an increase in SACT supply demand. The benefits of utilising dose banding to manage this increase in demand have been outlined in the NCCP Guidance document on Dose Banding.

The NCCP recognised that there was a need to develop dose banding guidance and implementation documents in order to:

- Have agreed National Dose Banding Tables in place
- Address service demand and streamline processes
- Expand the number of drugs that are included in the National Dose Banding Tables
- Aid in the management of increasing workload within hospital pharmacy aseptic compounding units through improved efficiency in SACT preparation by reducing the time spent on individual dose calculations and preparation
- Further expand the opportunity to purchase ready made products
- Increased cost effectiveness through reduced wastage

The NCCP recommend dose banding as a strategy to manage Aseptic Compounding Unit (ACU) capacity. This approach has been agreed at a national level by the Irish Society of Medical Oncology (ISMO) and the Irish Haematology Society (IHS).

This document outlines the recommended steps to be taken in the implementation of dose banding as well as addressing frequently asked questions (FAQs).

COVID-19 Tables

Please note that there is an abridged series of NCCP National Dose Banding Tables which have been amended for the COVID-19 situation. The dose bands in these amended tables have been expanded up to a variance of 10% to reduce the number of dose bands available, facilitate optimal use of outsource provider and to minimise wastage.

These amended dose banding tables have been agreed with ISMO and IHS. All dose bands contained in these tables are subject to local implementation and as deemed relevant to local practice. Please refer to the NCCP dose banding documentation and full tables for more detail www.hse.ie/nccpdosebanding.

2 Implementation of Dose Banding

2.1 Groundwork

- The Guidance document has identified the drugs suitable for dose banding and the associated Dose Banding Tables to be used. Identify which of these is applicable to your local practice.
- The Dose Banding Tables cover a broad range of doses, not all of which would be suitable to be kept as stock. Individual sites should identify their own high usage items and doses with a view to maintaining stock levels of those items to enhance throughput.
- Identify whether you plan to compound these drugs in-house or out-source the compounding to an external licensed manufacturer. This may involve carrying out a budget impact assessment for your site.
- Evaluate the potential impact of using pre-prepared doses on pharmacy workflow, turn-around times, advance preparation and patient waiting times (use capacity planning tools when available).
- Use and encourage multi-disciplinary collaboration in assessing impact.
- Identify additional storage requirements including fridge and shelf space.
- Liaise with medical and nursing colleagues to discuss proposed change and to identify training requirements.
- Develop a communication plan to inform and educate all staff on the proposed change. This should include medical, nursing and pharmacy staff.

2.2 Gaining Consensus and Consent

- Identify a local project manager (medical, nursing or pharmacy) to lead the introduction of the change.
- Identify a pharmacy “champion” to drive the change and to involve and include all relevant pharmacy staff.
- Identify a nursing “champion” to drive the change and to involve and include all nursing staff.
- Identify a medical “champion” to drive the change and to involve and include all relevant medical staff.
- Engage key stakeholders in all steps of the process relevant to their practice.

2.3 Clinical Governance

- Ensure the NCCP Guidance document is easily accessible to all end users.
- Develop/amend in-house SOPs to reflect the use of dose banding products.
- Define procedures to be followed in relation to dose banded products (See NCCP Guidance document Section 7.0 Procedure for Use of Dose Banding).
- Keep record of any errors or near misses associated with dose banding to ensure the introduction has not introduced any new systematic errors or risk.

2.4 Training and Communication

- Ensure that all prescribers are familiar with dose banding procedures.
- Ensure prescribers are aware that prescriptions for dose banded drugs will be adjusted to the agreed dose band as per locally agreed procedures. This may include adjustment by the pharmacist or nurse on prescription verification if not already dose banded[1].
- Prescriptions written for Oral Anti-Cancer Medicines for dispensing in the community which have not been dose banded (where applicable) may be amended to the agreed dose band by the pharmacist or nurse[1]. Any amendments made will need to be counter-signed by a physician prior to dispensing in the community.[2]
- Organise training sessions for new / rotational and / or locum staff
    - At initiation
    - At regular intervals to capture new staff or as part of induction training for all new staff.
- Communicate change effectively with all stakeholders including medical, nursing and pharmacy staff.
- Ensure dose banding tables are available in both paper and electronic form in all relevant clinical areas.
- Establish a schedule for review of dose banding practice.

2.5 Procedures to be followed at prescription writing and / or verification stage for products eligible for dose banding

- Prescribers should:
    - Calculate BSA as per standard local procedures.
    - Calculate the dose to be administered:
        - Dose band the dose to be administered[3].
        - Where a dose falls outside the recommended dose bands (due to reasons including, but not limited to; very low or very high BSA, very low or very high weight, dose of drug not commonly used), the

[1] The local SACT prescribing policy should include the agreement with regard to staff who may amend prescriptions for the purpose of dose banding.

[2] S.I No. 540/2003 – Medicinal products (Prescription and Control of Supply) Regulations 2003.

[3] The local SACT prescribing policy should include reference to the use of dose banding.

calculated dose using the appropriate method should be prescribed.

- Pharmacists or nurses verifying the prescription may amend the dose to the nearest dose band[4] if this step has not been completed by the prescriber, provided that this is in line with locally agreed procedures.
- If there are any queries, refer to the prescribing consultant.

2.6 Procedures to be followed at administration

- Verify dose as per standard local procedures. If the dose supplied differs to the dose prescribed, check the dose banding tables and verify that the dose supplied falls within the correct dose band. If they do not or if there are any further queries regarding the dose, liaise with the pharmacy and / or prescriber to verify dose prior to administration to the patient.

3 Frequently Asked Questions

3.1 Will I need extra storage space?

Additional space for both refrigerated and room temperature dose banded pre-prepared products may be needed to maximise the benefits (of extended shelf-lives of banded doses). Lead times for out-sourced products should be considered when setting local stock levels.

3.2 What is the licensed status of batch-produced SACT doses?

Batch-produced doses are unlicensed products[5]. Follow local procedure for dealing with unlicensed products.

3.3 My consultant does not wish to have dose banding utilised for a particular patient's drugs. How is this dealt with?

If there are clinical reasons why an individual patient is not considered suitable for dose banding by the treating consultant, they should write "**NOT FOR DOSE BANDING**" clearly on the prescription, along with their signature and date or as detailed in the local SOP governing dose banding. The rationale for this should be documented by the consultant as outlined in the local SOP.

[4] The local SACT prescribing policy should include the agreement with regard to staff who may amend prescriptions for the purpose of dose banding.

[5] All compounded products purchased form an external company are unlicensed products, including any dose banded products.

3.4 Nursing staff have raised concerns over the supply of two to three syringes for administration as an IV bolus to patients

This can be dealt with through training where correct procedure to safely recognise that the complete dose for a patient requires the administration of more than one syringe. The decision to use multiple syringes can be made locally by assessing demand and ease of supply of doses**.**

3.5 Do I have to keep the suggested syringe sizes for bolus injection drugs?

No, that is for local definition. The syringe sizes are suggested as a means to simply supply all doses within the dose bands using a stock of 6 different syringe sizes. Sites can evaluate locally if they want to use multiple syringes or a single syringe to supply the dose.

3.6 Are the dose banding recommendations mandatory for all sites.

The dose banding recommendations are intended for use by sites who choose to adopt them in order to assist capacity issues, improve efficiencies and to standardise and streamline prescribing at their site. Where dose banding is introduced, the National Dose Banding Tables should be utilised. If dose banding is already in use at a site, then it is recommended that they should move to the National Dose Banding Tables as soon as possible to facilitate standardisation of prescribing across the health service.

3.7 If I compound items on receipt of a prescription and apply a 24 hour expiry, is dose banding applicable to my site?

Yes, dose banding of items prepared may still be utilised as it will standardise the doses to be administered to patients and ensure doctors become familiar with the doses that are used irrespective of the site they work in. It will also facilitate the potential use of doses to be made available through cancellation or deferral of patients' treatment, subject to expiry.

3.8 If I outsource my compounding, do I need to purchase minimum amounts of each band.

This is for each site to agree with their preferred supplier.

3.9 Will I still be able to purchase patient specific labelled products from an external compounding supplier?

This is for each site to agree with their preferred supplier[6]. In the longer term, the use of dose banding may facilitate optimal use of outsourced capacity.

3.10 Why are there so many dose bands for some drugs e.g. PACLitaxel, CARBOplatin?

Some drugs are used in a very broad range of doses e.g. PACLitaxel 50mg/m^2 up to 200mg/m^2 or CARBOplatin AUC 1.5 up to AUC 7.5. A broad range of dose bands was required to accommodate this. Each site may identify the doses that are most used within their scope of practice.

3.11 My site supplies all products with closed system transfer devices attached. How is this dealt with for dose banded products?.

The selection and use of closed systems was outside the scope of this working group. The products supplied locally should be as agreed at your hospital and subject to local implementation. That may require:

- Attaching the closed system transfer device at compounding stage for items compounded locally.
- Attaching the closed system transfer device locally for products purchased in from an external compounding supplier.
- Agreement with your preferred supplier to have the products delivered, where possible, with the agreed closed system transfer device attached.

[6] Recommendation 77 of the NCCP Oncology Medication Safety Review details that "Outsourced products should be overlabelled where the label does not comply with the minimum requirements as detailed in Appendix 10" of that review.

3.12 Patient J D has a body surface area of 1.8m^2. The patient is to receive DOCEtaxel (75mg/m^2) and CycloPHOSphamide (600mg/m^2). How is this calculated within the dose bands?

JD has a BSA of 1.8m^2.

DOCEtaxel (75mg/m^2): 75x1.8 = 135 mg. By referring to the DOCEtaxel Dose Band Table, the Banded Dose recommended is 132 mg.

Dose Range (mg)	**DOCEtaxel Banded Dose (mg)**
127 - 138	**132**

CycloPHOSphamide (600mg/m^2): 600x1.8 = 1080mg. By referring to the CycloPHOSphamide Dose Band Table, the Banded Dose recommended is 1100mg.

Dose Range (mg)	**CycloPHOSphamide Banded Dose (mg)**
1051 - 1150	**1100**

3.13 Patient J D (BSA 1.8m^2) suffered toxicity following cycle 1 DOCEtaxel (75mg/m^2) and CycloPHOSphamide (600mg/m^2). The consultant requires a 20% dose reduction to be applied. How is this calculated within the dose bands?

Dose reduction is detailed in section 6.3 of the Dose Banding Guidance Document.

The method to be used should be defined locally and detailed in the SOP governing dose banding. One option for use is to apply the percentage reduction to the banded dose that was actually given to the patient as this represents the dose that led to the toxicity.

This method, if applied here:

	DOCEtaxel (mg)	**CycloPHOSphamide IV Infusion (mg)**
Cycle 1 Banded Dose	132	1100
20% dose reduction of banded dose	105.6	880

By referring to the DOCEtaxel Dose Band Table, the adjusted Banded Dose recommended is 104 mg.

Dose Range (mg)	**DOCEtaxel Banded Dose (mg)**
101 - 108	**104**

By referring to the CycloPHOSphamide IV Infusion Dose Band Table, the adjusted Banded Dose recommended is 840mg.

Dose Range (mg)	**CycloPHOSphamide Banded Dose (mg)**
811 - 880	**840**

In NCIS, the corresponding strength of the dose banding product can be selected at the verification stage.

3.14 How do I request additional drugs for consideration for inclusion in the National Dose Bands

Anyone wishing to suggest additional dose bands may do so by emailing oncologydrugs@cancercontrol.ie

3.15 How do I request expansion of the National Dose Bands for existing drugs

Anyone wishing to suggest expansion of an existing dose bands may do so by emailing oncologydrugs@cancercontrol.ie

3.16 Does NCIS support Dose Banding?

There are two main pathways for dispensing or preparing SACT in NCIS:

The Preparation Pathway

This pathway is used for SACT medications that are prepared by the pharmacy. No automatic rounding or dose banding is available in this pathway, but users are able to modify the calculated dose for the purposes of rounding or banding, during the physician or pharmacist verification steps.

The Dispensed Pathway

This pathway is used primarily for SACT medications that are supplied by external compounding companies. NCIS does not support tabulated rounding (as is used in target dose banding where a patient's dose is rounded to the nearest band for a defined dose

range), however products have been built into NCIS as strengths which correspond to the National Dose Banding Tables. Users are then able to select and dispense these doses as individual products.

Additionally, NCIS will suggest a product when using the dispensed pathway. The product with the least variance from the planned dose will be suggested (this may involve split products). On occasion, this may lead to a suggested product that differs from the National Dose Band, where this occurs it is a local decision whether to:

- accept the suggested product
- change the product to follow the National Dose Banding Tables
- choose an alternative product as indicated by the clinician or local policy.

Example wording for local process documents could be – “The Pharmacy Department will apply the NCCP Dose Banding, or a dose with lesser variance to the following products……..”

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