National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP IMPLEMENTATION AND FAQ DOCUMENT

DOSE BANDING FOR SYSTEMIC ANTICANCER 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

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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. As detailed in the Guidance document, the use of Systemic Anti-Cancer Therapy (SACT) has risen significantly in recent years. While this has brought undoubted benefits to patients, it also presents a challenge to patient safety as the number of SACT drugs expands and the use of oral SACT increases.

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
- 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
- Further expand the opportunity to purchase ready made products

The NCCP recommend dose banding as a strategy to manage chemotherapy 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).

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 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 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 calculated dose should be prescribed.

[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 .

- 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.
- 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.
- If the dose is as per agreed dose banding tables, proceed with administration of treatment in line with standard local procedures.

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 felt to be 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 that 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.

No. 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 make 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].

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.

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.

[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.

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)	**Docetaxel 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 (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 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 How dose NCIS apply dose banding

The National Dose Bands have been built into NCIS as strengths of a product. NCIS will not automatically apply a dose band; however at the point of medicines verification an approved dose band may be selected.

Please note that as NCIS suggests the dose with the least variance rather than referring directly to the national dose banding tables, the suggested NCIS dose may differ from the recommended dose band. It is a local decision whether or not to accept NCIS prompts or to manually change the NCIS dose band to follow the national dose banding tables

4 References

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