NCCP IMPLEMENTATION AND FAQ DOCUMENT DOSE BANDING FOR SYSTEMIC ANTICANCER THERAPY (SACT)

This is a draft document subject to agreement

Version	Date	Amendment	Approved By
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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. Whilst 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.

In light of this 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 and
- 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 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 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 pharmacy project manager to lead the introduction of the change
- Identify a nursing "champion" to drive the change and to involve and include all nursing staff.
- Enagage 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
- 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 on prescription verification (if it is not already dose banded). Prescriptions written for Oral Anti-Cancer Medicines for dispensing in the community which have not been dose banded (where applicable) can be amended by the hospital pharmacist. Any amendments made will need to be counter-signed by a physician prior to dispensing in the community.¹
- Organise training sessions for new/ rotational and/ or locum staff
 - At initiation

- o 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.

¹ S.I No. 540/2003 – Medicinal products (Prescription and Control of Supply) Regulations 2003.

Establish a schedule for review of dose banding practice.

2.5 Procedures to be followed at prescription writing and/or verification stage

- Prescribers should:
 - Calculate BSA as per standard local procedures.
 - o Calculate the dose /m²
 - Obse band any doses to be prescribed as per current dose banding tables agreed (for drugs that are included in the dose banding tables). For patients where the 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), liaise with the pharmacy department to coordinate drug supple particularly where there is no in-house compounding unit.
- For prescriptions received for products to be compounded or to be dispensed in-house that have not been dose banded, the pharmacist may amend the dose to the nearest dose band following their verification checks (as per the Oncology Medication Safety review report appendix 6).
 Details of how this is to be done should be defined locally and detailed in the SOP governing dose banding.
- 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

Q. Will I need extra storage space?

A. Additional space for both refrigerated and room temperature dose banded preprepared products will be needed to maximise the benefits (of extended shelflives of banded doses). Lead times for out-sourced products may increase the amount of pre-prepared doses held in stock.

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

A. Batch-produced doses are unlicensed products. A full audit trail of source material, manufacture and dispensing to individual patients must be maintained in the documentation. Follow local procedure for dealing with unlicensed products.

Q. My consultant doesn't want dose banding to be applied to a particular patient. How is this dealt with?

- A. 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.
- Q. Nursing staff have raised concerns over the supply of two to three syringes for administration as an IV bolus to patients Do I have to keep the suggested syringe sizes for bolus injection drugs?
- A. 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.

1. References

- 1. NCCP. NCCP Oncology Medication Safety Review Report. 2014.
- 2. Gillian A. BOPA Toolkit: How to Implement Dose Banding of Chemotherapy. Network Pharmacist (NELCN) on behalf of Network Cancer Pharmacists. 2008.
- 3. SOPPG. Guidelines for Dose Banding of Systemic Anti-Cancer Therapy Development and Governance Framework. 2015.
- 4. Plumridge R, GJ S. Dose Banding of cytotoxic drugs: A new concept in cancer chemotherapy. Am J Health-Syst Pharm. 2001;58(Sep 15).
- 5. Ratain M. Body Surface Area as a basis for dosing of anti-cancer agents: science, myth or habit. J Clin Oncol. 1998;16(2297-9).
- 6. Shuter B, Aslani A. Body surface area: Du Bois and Du Bois revisited. European Journal of Applied Physiology. 2000;82(3):250-4.
- 7. Griggs JJ, Mangu PB, Anderson H, Balaban EP, Dignam JJ, Hryniuk WM, et al. Appropriate Chemotherapy Dosing for Obese Adult Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline. Journal of Clinical Oncology. 2012;30(13):1553-61.
- 8. Williamson S, Polwart C. Guidelines for the Dose Banding of Cancer Chemotherapy. NECN. Vers 1.4.