

SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer

SHPA Committee of Specialty Practice in Cancer Services

These guidelines are standards of professional practice and not standards prepared by Standards Australia. They are not legally binding.

These standards describe activities consistent with good practice for the provision of pharmacy services to patients receiving oral chemotherapy for the treatment of cancer. They must be read in conjunction with standards of practice relating to clinical pharmacy, clinical oncology pharmacy services, investigational medicines and technical aspects involved in the safe handling of cytotoxic drugs in pharmacy departments.^{1,4}

These standards supersede the previously published SHPA guidelines for counselling patients receiving drugs used in the treatment of neoplastic disease: a pharmacist's guide to advisory labels and patient information.⁵

It is recognised that oral chemotherapy may be used as immunosuppressive therapy in other conditions such as rheumatoid arthritis and systemic lupus erythematosus. It is outside the scope of these standards to make specific recommendations for these areas, however, the principles of these standards are applicable to the treatment of conditions other than cancer.

INTRODUCTION

Oral chemotherapy is being increasingly used as a treatment modality for a variety of cancers and forms part of many chemotherapy protocols. It offers advantages to patients and staff as it does not require admission to hospital and places a lesser burden on pharmacy and nursing staff in busy chemotherapy reconstitution and day units. Oral chemotherapy carries the same risk as parenteral chemotherapy in terms of toxicities and potential for harm from medication errors due to the narrow therapeutic index of these drugs. Oral chemotherapy must be subject to the same stringent prescribing and checking procedures as chemotherapy administered by other routes.^{6,7}

Home-based treatment with oral chemotherapy may continue for weeks at a time without direct professional supervision. The intermittent treatment that is characteristic of cancer chemotherapy may be hard for some patients to understand and misinterpretation of dosing carries the risk of serious harm. Education of patients and/or primary carers about the use of oral chemotherapy is critical to patient safety.

Oral chemotherapy drugs present a health and safety risk to staff, carers and patients handling them, although the risk of exposure is minimal. Health and Safety guidelines must be followed to minimise the risk of exposure.

OBJECTIVES

These standards describe the minimum requirements for the provision of pharmaceutical care to patients receiving oral chemotherapy for the treatment of cancer. These standards offer guidance for:

- staffing requirements for service provision including skills, competency and resource access;

- requirements for verifying prescriptions and supplying medication to ensure optimal therapy and to minimise medication errors;
- health and safety aspects relating to the handling and supply of oral chemotherapy; and
- counselling and education of patients receiving oral chemotherapy and/or their carers.

EXTENT AND OPERATION

This standard applies to all pharmacists providing oral chemotherapy and targeted therapy to cancer patients. For the purposes of this standard the term 'oral chemotherapy' is used to refer to all medicines which have antitumour activity that are administered to cancer patients via the oral route. It should be noted that the list of oral cytotoxic drugs in Appendix 1 is not exhaustive and may not include medicines introduced into clinical practice after this standard was published.

POLICIES AND PROCEDURES

The pharmaceutical care of patients receiving oral chemotherapy for cancer includes prescription verification, dispensing and education of patients. This must be carried out by a pharmacist with the appropriate training and skills in cancer chemotherapy as defined by the SHPA Standards of Practice for the Provision of Clinical Oncology Pharmacy Services.² If such a pharmacist is not available then a qualified pharmacist with competency in chemotherapy treatment and with access to specialist advice relating to cancer care must carry out this task. Staff with insufficient knowledge or experience in cancer treatment must not be delegated to manage the supply of oral chemotherapy. The usual professional requirements of a pharmacist when dispensing prescriptions also apply.

Prescription Verification

Prior to dispensing a prescription for oral chemotherapy it must be screened by a pharmacist with experience in cancer chemotherapy who will accept responsibility for the clinical safety of the prescription. To ensure optimal and appropriate treatment, all chemotherapy must be prescribed in the context of a referenced protocol and ideally on a specifically designed chemotherapy prescription form. The prescriptions must state clearly for each course of treatment, the drug, dose, route and frequency of administration, intended start date, duration of treatment, and where relevant, the intended stop date. Pharmacists must have access to a documented treatment plan and to full copies of the relevant protocol. Pharmacists must:

- ensure that prescribed doses, treatment intervals and administration details are appropriate to the patient's demographics, tumour type, haematological and biochemical profile, organ function and chosen treatment protocol;
- verify that the maximum and cumulative doses of all chemotherapy doses prescribed are not exceeded;
- check that all chemotherapy drugs listed in the protocol have been prescribed including those to be administered by other routes;

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- check that additional supportive drugs relevant to the treatment protocol have been prescribed and are appropriate for the protocol, the length of the course and the patients, e.g. antiemetics, colony growth stimulating factors;
- be aware of the toxic and therapeutic effects of the medicine and identify interactions with other drugs;
- ensure that the appropriate medicines are supplied in an efficient and timely manner according to the patient's treatment plan; and
- verify with the original prescriber any anomalies identified during this checking process. Incorrect or missing details must be corrected by the prescriber prior to dispensing.

All cancer chemotherapy must be subject to a second independent check to verify all prescribing and dispensing details. The second check must include a clinical check, label check, contents check and a check to ensure the correct number of tablets has been supplied. Pharmacists carrying out this task must have the training and skills in cancer chemotherapy. If such a pharmacist is not available then a pharmacist or nurse with competency in chemotherapy and with access to specialist advice relating to cancer care must carry out this task.

Where a patient is admitted to hospital and is already receiving oral chemotherapy the original prescriber must be contacted to verify all details of the treatment including the dose, frequency of administration, duration of treatment and, where relevant, the intended stop date. A documented treatment plan and a copy of the relevant protocol must be obtained before supply or administration of the medicine is made.

Quantity to Supply

Pharmacists should only supply the quantity of tablets/capsules requires for that cycle of treatment. The use of whole packs may pose a risk to patients if they contain more tablets than are needed for the cycle. The decision to issue whole packs (as opposed to the exact quantity) must be based on the judgement of pharmacists experienced in cytotoxic chemotherapy and may depend on local policy.

If a whole pack is issued then the following label must be added: *You will have xxxx number of tablets remaining at the end of this course. Please return unused tablets to your pharmacist for destruction or for use for your next course of chemotherapy.*

Where a hospital inpatient commences a course of oral chemotherapy that will continue after discharge from hospital then the total quantity of tablets/capsules the patient requires for the entire course should be supplied. In these circumstances it is appropriate to supply oral chemotherapy with directions for outpatient use and instruct the nursing staff to return the remaining tablets to pharmacy for inclusion in the patient discharge medication on discharge from hospital. If an inpatient is receiving oral chemotherapy at the time of discharge to complete a course that has commenced as an inpatient it is important to consider the number of tablets the patient needs from the time the patient is due to leave the hospital, taking into account any morning or midday doses.

Where a patient is admitted to hospital and is already receiving oral chemotherapy the doctor must make a decision as to whether the treatment should continue. In many cases this may require consultation with the original prescriber. Where a decision is made to continue with treatment the patient's own supply should be used wherever possible. Pharmacists should verify the suitability of the medicine for use by patients in the hospital. If a new supply is required the quantity supplied must be appropriate for that course. Oral cytotoxics must not be made available as inpatient or ward stock.

Repeat prescriptions preferably should not be issued for oral chemotherapy due to the risk of mis-dosing. However, many prescribers may use this option within the Pharmaceutical Benefits Scheme (PBS) regulations and this will depend on local policy. Chemotherapy doses may change according to blood results, adverse effects and therapeutic response. If a repeat prescription is presented for a second or subsequent course then the pharmacist must confirm with the prescriber and patient that there has been no change to the dose or overall treatment since the original prescription was issued and before supply is made. If treatment is changed or stopped the patient must be directed to destroy any repeats or return them to the doctor or pharmacy to avoid any inadvertent dispensing.

Labelling

Labelling for cytotoxic chemotherapy should use generic names particularly where there is more than one manufacturer for the product. Where local policy dictates the use of trade names a reference should be included in the labelling to the generic name. As well as standard labelling requirements the directions on the label must include:

- clear and unambiguous dosing instructions; 'as directed' must never be used regardless of the doctor's instruction or of the patient's knowledge of the dosing regimen;
- the intended period of treatment (i.e. number of days);
- start and stop dates for short-term or intermittent treatment. (e.g. if the drug is to be taken on days 1 to 4 inclusively then the label must specify the actual calendar dates);
- the total dose required. If patients are required to take two different strengths of tablets to make up the dose (e.g. capecitabine 150 mg and 500 mg) then the instructions must be labelled with the number of tablets to take and the total dose. Steps must be taken to highlight different strengths of the same tablets/capsules to aid patient understanding;
- all boxes/bottles must contain a label. Boxes must never be taped together with a label on one box. When more than one container of the same medicine is given then the following label (or similar) must be used: *This is x of y number of containers containing the same medicine. Please use the contents of one container before starting another;*
- doses of chemotherapy that are intended to be taken weekly (e.g. methotrexate, lomustine, vinorelbine) must include on the label the term 'once a week' and specify the day the dose is due, e.g. once a week on a Tuesday. An additional label should also be added: *This dose of 'drug x' is taken WEEKLY. Check your dose carefully;*
- a label indicating appropriate storage requirements must also be added (if required);
- cautionary and advisory labels as required must be added to the container; and
- dispensed containers of cytotoxic drugs (e.g. capsules) must be clearly labelled with a cytotoxic warning sticker in accordance with local health and safety requirements. Suggested labelling is a permanent, adhesive purple cytotoxic warning label with the distinctive warning: *Cytotoxic, Handle with Care.*

Health and Safety

Oral chemotherapy must be handled in a manner which avoids skin contact, the liberation of aerosols or powdered medicine into the air and cross-contamination with other medicines. Preference should be given to manufacturers that package tablets and capsules in protective strip packaging. If there is a need to cut the blister strips then it must be ensured that the tablets/

capsules are not exposed. The use of gloves to dispense oral cytotoxic drugs is recommended and hands must be washed thoroughly after each dispensing.

Loose tablets/capsules must be counted using designated counting trays and spatulas labelled specifically for that purpose. Counting machines must not be used and the actual tablets or capsules must not be touched. All trays and spatulas must be cleaned after each use with water and detergent.

When tablets/capsules are supplied in glass bottles then pharmacists must confirm whether other containers are suitable for dispensing or whether it is essential that the glass bottles be used to avoid any adverse storage effects on the drug.

Child-proof caps must be used when dispensing non-blister packs of containers of oral chemotherapy for use outside the healthcare setting.

When a dose administration aid (e.g. Webster pak) is needed by the patient then this must be filled by the pharmacist dispensing the chemotherapy and labelled with relevant instructions and a cytotoxic warning label. Other non-cytotoxic medication must not be placed in the same pack.

Crushing or cutting of tablets and opening of capsules must not be carried out in the pharmacy outside a Class II cytotoxic drug safety cabinet because of the unacceptable risk of exposure. In situations where a fraction of a manufactured dose has been prescribed then an alternative formulation should be sourced or the prescriber should be contacted to discuss alternate dosing regimens that use whole tablets. Doses may be rounded up or down where the actual dose is close to the strength of a whole tablet. Alternate day dosing to make up the total weekly dose is a method that is frequently employed. (e.g. if cyclophosphamide is to be given as 175 mg daily for 2 weeks this may be given as 200 mg on one day and 150 mg on the next as alternate day dosing to ensure the correct total dose). This method however is not suitable for all cytotoxic drugs and specialist advice must always be sought.

If the medicine is to be administered via a nasogastric tube, or if patients are unable to swallow tablets/capsules, appropriate formulations must be obtained from manufacturers with the facilities to compound non-sterile cytotoxic drug preparations. Currently the availability of such facilities is limited. A cytotoxic drug safety cabinet used to prepare aseptic parenteral cytotoxics should not be used to prepare non-sterile items. The risk of particulate contamination and cross contamination of the cabinet and the cleanroom is very high.

All layers of the packaging and containers for use in hospital and outside the health care setting must have a cytotoxic warning label, including the outer bag that contains the supply.

Oral cytotoxic drugs must be identifiable by all workers and must be stored on designated shelves or in an area clearly labelled with cytotoxic stickers

Patient Education and Information

All patients and/or carers must be educated on how to take their medication to ensure they receive optimal benefit of chemotherapy and to minimise any opportunity for medication administration errors. This education must be carried out by staff who have received appropriate training.

When medicines are handed to patients by non-pharmacy staff or where the supply is made to a non-oncology ward in a hospital or nursing home, procedures must be in place to ensure nursing staff are aware of the nature and effects of the treatment being given and steps to take in case of an adverse event.

Chemotherapy has many unavoidable toxicities and patients must always be counselled before they start treatment as to the overall nature of these effects and what to expect. Pharmacists must ensure that they work in conjunction with

the medical and nursing staff in providing this type of information to ensure accuracy and appropriateness. In some cases, patient counselling may be carried out by the oncology pharmacist or as part of a formal patient education session but this will depend on local policy.

Clear written instructions and/or medication guides for both chemotherapy and supportive therapy are essential in this setting along with the use of consumer medication information (CMI).⁸ Diaries may be used by patients to help them remember when to take medications and to record any adverse effects.

The nature and context in which chemotherapy drugs are used often limits the availability or suitability of CMIs, as chemotherapy may be used outside the Therapeutic Goods Administration indications or as part of a protocol which may induce possible effects not listed in CMIs. Guidance on how to use CMI may be found in the SHPA Standards of Practice for the Provision of Consumer Medicines Information by Pharmacists in Hospitals.⁸

CMI must be given if available, and in addition institutions may have developed their own information leaflets which are suitable for use. Pharmacists must ensure that information contained in any such leaflet has been verified and approved by the hospital drug and therapeutics committee or similar. Professional judgement must be used when deciding on appropriate and relevant information. Patients may be given a wealth of information from many members of the team caring for them and may become confused with too much information.

When counselling pharmacy staff must ensure that patients or carers fully understand the tips listed in Appendix 2.

Patients must be provided with details of accessible 24-hour contact with medical, nursing and pharmacy staff to whom they can direct queries. This information must be given on the first visit and reinforced on subsequent visits. Questions on compliance, treatment tolerability, and adverse events must always be addressed at each visit to the pharmacy.

RESOURCES

Resources should be sufficient to ensure the above procedures are able to be performed in a safe and accurate manner for staff and patients.

STAFFING STRUCTURE AND LEVELS

There should be sufficient suitably qualified staff to dispense all prescriptions in the manner described above.

STAFF TRAINING AND EDUCATION

Pharmacists dealing with oral cytotoxics must have appropriate training and skills in cancer chemotherapy as defined by SHPA Standards of Practice for the Provision of Clinical Oncology Pharmacy Services. If such a pharmacist is not available then a qualified pharmacist with competency in chemotherapy treatment and with access to specialist advice relating to cancer care must carry out this task. Staff with insufficient knowledge or experience in cancer treatment must not be delegated to manage the supply of oral chemotherapy. Nurses and other staff in the inpatient setting should be educated on the precautions necessary to minimise the risks associated with handling and administering oral chemotherapy.

QUALITY

The fundamental quality components of the provision of pharmaceutical care of patients receiving oral chemotherapy for cancer are referred to in previous sections. Implementation of the standard ensures the quality of service provision. Further quality principles and measurements applicable to this standard are referred to in the SHPA Standards of Practice of Clinical Pharmacy and for the provision of clinical oncology services.^{2,3}

DOCUMENTATION

Documentation should include the treatment plan and a copy of the relevant protocol where appropriate. Provision of a CMI and other relevant patient information must be noted.

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Appendix 1. Oral cytotoxic drugs

Busulfan	Idarubicin
Capecitabine	Lomustine
Chlorambucil	Melphalan
Cyclophosphamide	Mercaptopurine
Dasatinib	Methotrexate
Etoposide	Procarbazine
Fludarabine	Temozolomide
Hydroxyurea	Thioguanine
Partially targeted treatments (e.g. imatinib, gefitinib)	Vinorelbine
Investigational oral cytotoxic drugs available via the Special Access Scheme or as part of clinical trials.	Immunomodulatory drugs (e.g. thalidomide)

It does not include hormonal or steroidal drugs.

Appendix 2. Counselling points for pharmacy staff

The medication name and indication. If the medication is part of a protocol, then the protocol name should be provided.

How and when to take their medication. Some patients may find it difficult to comprehend the concept of repeated short treatment courses with 'gaps' between them or the concept of treatment days (i.e. Cycle 1 Day 8).

The duration of treatment.

What to do in the event of missing one or more doses.

What to do in case of vomiting after taking a dose.

The need to swallow tablets/capsules whole and not to chew. The risks of crushing tablets and mixing with food or emptying the contents of capsules into food or drink must be highlighted.

Important interactions (food-drug, drug-drug, drug-herb).⁹ The risks of taking additional medicines not prescribed by their doctor (including complementary therapies) and of the need to inform health professionals about all their current treatments. It is useful to provide and maintain a patient medication profile where any changes in medication can be recorded.

Expected adverse effects, strategies for managing them and when to seek professional help. Since monitoring is less frequent with oral therapy, patients may need to seek help early if adverse effects develop that may necessitate a break from treatment.

When to take supportive medication such as antiemetics.

The need for and how to obtain further supplies.

The principles of safe handling, storage and disposal. They must be advised:

- to store all medications including any needing refrigeration in a secure manner away from children;
- to avoid or keep to a minimum handling of tablets/capsules by any other member of the family or friends other than themselves;
- to always wash their hands after handling the tablets/capsules;
- to store empty containers and unused medication in a strong designated container or bag and return these to the hospital or pharmacy for disposal; and
- about the health and safety aspects of dealing with bodily waste.

Expected tests during treatment, e.g. blood tests.

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