

Quality use of medicines notice

Information for health services

Caution with oral chemotherapy for cancer

Audience	Chief Executive Officers, Directors of Clinical Governance, Directors of Medical Services, Directors of Nursing, Directors of Pharmacy, Quality and Risk Managers, Oncology Medical Staff, Nurses and Pharmacists.
This notice applies to	<ul style="list-style-type: none"> Orally administered chemotherapy for cancer which is a term used to describe the orally administered cytotoxic and non-cytotoxic antineoplastics (including monoclonal antibodies and molecular therapies) in the Australian Medicines Handbook. (1) Patients receiving oral medicines for cancer wholly or partly in an outpatient or community setting.
Date	November 2010
Further Information	www.health.vic.gov.au/qum/initiatives/hrm.htm

Introduction

Critical errors have occurred during prescribing, dispensing and self-administration of oral chemotherapy for cancer (orally administered antineoplastic medicines as cancer treatment). Overdosing can result in serious toxicities or fatal outcomes. Under dosing influences the effectiveness of the treatment regimen.

Reported errors

- Incorrect dosages or schedules of oral chemotherapies have been prescribed.
- Unclear or insufficient information regarding the treatment has been provided to the health professionals, patients and carers who manage supply and administration in the general hospital or community setting.
- Prescribed dosage instructions have been misinterpreted and incorrect doses or treatment durations self-administered.

How prescriptions for oral cancer treatment can cause significant harm or death

Case study one

A rural patient under the care of a metropolitan hospital oncologist, was prescribed oral capecitabine monotherapy as palliative treatment for metastatic breast cancer. The first cycle of treatment was dispensed from the hospital pharmacy and detailed verbal and pharmacy label instructions were provided to take the tablets for two weeks followed by a week of rest. The patient misunderstood the directions and filled the repeat prescription at her local pharmacy on finishing the initial supply of tablets, continuing the chemotherapy without a rest period. The patient was visited by district nursing staff several weeks later and found to require immediate referral for treatment of diarrhoea and mucositis. Fortunately, the patient recovered.

Contributing factors

- The balance between achieving maximal anti-cancer effect and acceptable toxicity leaves limited margin for error. There may be a misconception that orally administered cancer chemotherapy medicines are less toxic and does not carry the same level of risk as cancer chemotherapy given by other routes.⁽²⁾
 - Orally administered cancer chemotherapy dosage schedules are unlike other oral medicines and may be difficult for patients to manage. They are often complex, intermittent and schedules may vary according to indication and stage of cancer being managed.
 - The abbreviations and acronyms used to describe complex scheduling and the nomenclature associated with cancer chemotherapy regimens can be easily misinterpreted.
 - Oral chemotherapy permits patient self-administration at home where drug dosage or scheduling errors are unlikely to be detected and may continue for weeks at a time without direct professional supervision.⁽²⁾
 - The specialist oncology multi-disciplinary team knowledge, systems and processes developed to minimise the risks associated with cancer chemotherapy in specialist cancer treatment units may be bypassed when supply and administration of oral chemotherapy for cancer occurs in the general hospital or community setting.
 - The large variation in orally administered cancer chemotherapy dosage schedules may mean that ambiguous prescriptions and errors are less easily detected.
- The health care professionals, patients and carers involved in the supply and administration of orally administered cancer chemotherapy in the general hospital or community setting may not have access to the patient treatment plan such as the chemotherapy protocol which details; when to be given, dates and duration of treatment, patient parameters, the timing and requirement for tests and information on treatment variations.

Moving from potential harm to safe care

Many organisations have implemented safety controls for the prescribing and supply of orally administered cancer chemotherapy, however, it is recommended that all organisations evaluate their current procedures against the recommendations below. Successful safety improvements require the development and implementation of sustainable procedures that are reviewed regularly and have commitment from the range of personnel involved in cancer chemotherapy.

Case study two

A patient was prescribed capecitabine and lapatinib for metastatic HER2 positive breast cancer that had failed to respond to trastuzumab. The protocol directs that capecitabine is to be given for two weeks followed by a week of rest and lapatinib continuously for three weeks. Unfortunately, only sufficient lapatinib was prescribed and dispensed for two weeks of treatment. The patient was unaware of the error and self-administered the two medicines for two weeks followed by a week of rest. The error was detected when the patient returned to the pharmacy to fill the repeat for the next cycle of treatment by a pharmacist familiar with the protocol.

Recommendations for oral chemotherapy for cancer

Organisational

1. Only health practitioners with the appropriate knowledge and skills in prescribing, dispensing and administration of oncology medicine should undertake or directly oversee these tasks. ⁽²⁾
2. All staff caring for the patient should have access to the relevant patient information including the diagnosis, patient's history, laboratory results and treatment plan. ⁽²⁾
3. Ensure 24 hour contact can be made with multi-disciplinary oncology staff for enquiries from patients or other health practitioners.

Prescribing oral chemotherapy for cancer for an outpatient or community setting

1. Ensure the prescription is clear and unambiguous:
 - use generic names
 - ensure calculated dosages are rounded to strengths available ⁽²⁾
 - write the dose, frequency and duration and number of cycles of treatment in full ⁽³⁾
 - specify the start and stop dates for the duration of treatment, and the number of days 'off treatment' ⁽³⁾
 - only use accepted abbreviations. ⁽⁴⁾
2. Ensure appropriate supportive therapies are prescribed (for example, antiemetics).
3. Attach a treatment plan to the prescription (which may be in the form of a letter to the general practitioner (GP)). A copy of this information should also be sent to the patient's GP.
The treatment plan should contain sufficient information to permit an independent check of the prescribed regimen and clearly communicates the ongoing treatment plan to

health practitioners that may provide patient care in between appointments (for example, another prescriber, a community or general hospital pharmacy, or community nursing service) including:

- patient name and other unique identifiers (for example, date of birth) ⁽²⁾
 - the diagnosis/indication ⁽²⁾
 - the prescribed protocol/regimen
 - the calculated dose and method for calculating (for example, in mg/m² or mg/kg)
 - patient height and weight
 - required laboratory tests and timing relative to the treatment cycle
 - management of test results that fall out of the normal range, patient weight fluctuations and side effects (for example, supportive treatment, emergency contact details, instructions on when to refer to an acute care setting and conditions that require dose modifications)
 - documentation of any treatment variations ⁽²⁾
 - timing of next specialist appointment
 - name and contact details of the specialist completing the treatment plan. ⁽²⁾
4. Take extra care to verbally explain and provide written instructions to patients, particularly those with cancer involvement of the central nervous system (CNS), and their carers.
 - Include cycle length, the number of days on active treatment, the days that the patient is not to take treatment, and any laboratory test requirements

- explain expected side effects, how to take supportive medication and who to contact in the event of an emergency or severe adverse effects ⁽²⁾
- a calendar chart indicating the days on which active treatment should be taken can be beneficial.

Case study three

A patient with a brain tumour was prescribed temozolomide 100mg/m² for five days every 28 days (five days active treatment followed by a 23 day rest period). The patient had previously taken temozolomide continuously when prescribed as part of combined chemo-radiotherapy. The patient took the first five days of treatment, then re-presented to the general hospital outpatient pharmacy for another five days supply. The higher dose was dispensed twice more before the patient returned to the oncologist for a review, where the error was discovered.

Ensure patient understanding of the prescription and treatment plan

Health service processes should support nursing or pharmacist review of the prescription and treatment plan with the patient and/or carer to ensure clarity of instructions and reinforce patient's understanding.

Dispensing oral chemotherapy

1. Perform a check of the prescription against the treatment plan.
2. Ensure that supportive therapies have been prescribed.
3. Review other medicines taken by the patient (including over the counter and herbal) for potential drug interactions.
4. Access relevant laboratory results (which may include FBE with differential, U&Es with Cr, LFTs and pregnancy tests) before dispensing the prescription. In the case of variances to expected or reference levels, contact the prescriber for further directions.
5. Where possible, provide only the required quantity of cancer chemotherapy to complete a given cycle, (rather than the PBS quantity/manufacturer pack which may exceed requirements).
6. Ensure directions for use are clear and that dispensed label directions for intermittent therapies include the start and stop calendar dates.
7. Clearly identify cytotoxic medicines with a purple cytotoxic (ancillary) label. ⁽²⁾
8. Ensure the patient and/or carer understands the cycle length, the number of days on active treatment, when not to take treatment, management of expected side effects, any laboratory test requirements

and the recommended process for obtaining further medication needs.

Take particular care when explaining instructions to patients with cancer involvement of the central nervous system (CNS). If not already provided, provide clear written information regarding the name and indication for each medication and complete a calendar chart indicating the days on which active treatment should be taken.

9. Provide instructions for the safe handling, storage and disposal of medication.

Actions – health services should address

- Ensure there is a policy about the process for prescribing, dispensing and administration requirements of oral chemotherapy for cancer.
- Ensure that prescribing, dispensing and administration of oral chemotherapy for cancer treatment is undertaken by staff with the appropriate competencies.
- Ensure there is a process for the training and credentialing of these health professionals.
- Ensure there is a policy based on best practice about the education and provision of information to patients and/or carers.
- Ensure there is a policy based on best practice regarding the handover of treatment plan information to community practitioners.
- Ensure that any errors or near misses associated with the prescribing, dispensing and administration of orally administered cancer chemotherapy are reported in the hospital's incident reporting system and reviewed by the medication safety committee.

Clinical Governance, Quality Use of Medicines, Medication Safety, Drug and Therapeutics Committees and directors of medical services, pharmacy and nursing

- Ensure an individual or committee is designated to complete the Oral Chemotherapy for Cancer Audit Tool (available at: www.health.vic.gov.au/qum/initiatives/hrm.htm) to evaluate practices for oral chemotherapy for cancer in your organisation.
- Completing the audit tool may require some local gathering of evidence (such as sample audits) to confirm adherence with existing policies and guidelines.
- Assess the benefits and risks of current practices of oral cancer treatment prescribing, supply, patient education and handover to community practitioners in your organisation and review these practices in accordance with the recommendations of this notice.
- Consider the recommendations from the notice which are not in place in your organisation. Decide whether these are relevant to your service.
- Determine an action plan to implement recommendations your organisation plans to adopt. Ensure each action is allocated to a responsible committee or individual.
- Use the findings of the audit to regularly review and feedback to those committees with the responsibility for action.
Note: Recommendations are not compulsory. Other innovative solutions may be implemented to reduce the risks with orally administered cancer chemotherapy. Ensure these are documented on the 'Audit tool.'

Other governance issues to improve oral cancer chemotherapy safety

- Ensure a formal process exists for approving guidelines, procedures and written information leaflets before use in your organisation.
- Oral cancer treatment guidelines and procedures should become part of your organisation's training program. They should be included in orientation and continuing education sessions for relevant clinical staff.
- Assess and ensure the competency of medical, nursing and pharmacy staff in their roles and responsibilities for oral chemotherapy for cancer treatment, according to your guidelines.
- Ensure a reporting process is designed to capture orally administered chemotherapy errors and near misses in your organisation. Use the reported events to develop error prevention strategies.

Further information

- Drug Information Service, Pharmacy Department, Peter MacCallum Cancer Centre, East Melbourne, Victoria
- Society of Hospital Pharmacists of Australia (SHPA) Committee of Specialty Practice in Cancer Services, Standards of Practice for the Provision of Pharmaceutical Care of Patients Receiving Oral Chemotherapy for the Treatment of Cancer. *J Pharm Pract Res* 2007; 37(2): 147-50.
- The Cancer Council Victoria (TCCV) [Internet]. Melbourne, Victoria: Cancer Council Victoria [cited 2010 November 23]. Available from: www.cancervic.org.au/
- Cancer publications [Internet]. Canberra, ACT: National Health and Medical Research Council (NHMRC) [cited 2010 November 23]. Available from: www.nhmrc.gov.au/publications/subjects/cancer.htm
- Cancer Treatment Plan and Summary Templates, [Internet]. Alexandria, VA: American Society of Clinical Oncology (ASCO); March 2008 [cited 2010 November 23] Available from: www.asco.org/ascov2/Practice+&+Guidelines/Quality+Care/Quality+Measurement+&+Improvement/Chemotherapy+Treatment+Plan+and+Summary/Cancer+Treatment+Plan+and+Summary+Resources
- Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines. [Internet]. British Oncology Pharmacy Association (BOPA); January 2010 [cited 2010 November 23]. Available from: www.bopawebsite.org/tiki-page.php?pageName=Position+Statements
- Patient Information – All About Oral Chemotherapy, [Internet]. Sydney, NSW: Cancer Institute NSW Patients and carers, Resource (ID 492) [cited 2010 November 23]. Available from: www.eviq.org.au/
- GP Information sheets. Peter MacCallum Cancer Centre, East Melbourne, Victoria. [cited 2010 November 23]. Available from www.petermac.org/informationaboutchemotherapyforgps
- Cancer Institute NSW Cancer Treatments Online (evi Q) [Internet]. Sydney, NSW: Cancer Institute NSW [cited 2010 November 23]. Chemotherapy Protocols and Patient Information. Available from: www.eviq.org.au/
- Department of Health, 2008. Victorian Clinical Governance Policy Framework, Enhancing Clinical Care. Victorian Government Department of Health, Melbourne. [cited 2010 November 23]. Available from: www.health.vic.gov.au/clinrisk/publications/clinical_gov_policy.htm
- Department of Health, 2009. Credentialing and Defining the Scope of Clinical Practice for Medical Practitioners in Victorian Health Services – a Policy Handbook. Victorian Government of Department of Health, Melbourne. [cited 2010 November 23]. Available from: www.health.vic.gov.au/clinicalengagement/downloads/dhs_credentialling.pdf

References

1. Rossi, S (Ed.) (2010). Australian Medicines Handbook (Electronic Edition). Adelaide, Australian Medicines Handbook Pty Ltd.
2. Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy [Internet]. Surry Hills, NSW: Clinical Oncological Society of Australia (COSA); November 2008 [cited 2010 November 23]. Available from: www.cosa.org.au/cosa_assets/files/About%20us%20-%20publications/Guidelines%20for%20Safe%20Prescribing2008.pdf
3. National Patient Safety Agency. A themed review of patient safety incidents involving anti-cancer medicines (1 November 2003-30 June 2008). Executive Summary. October 2010. [cited 2010 November 23]. Available from: www.nrls.npsa.nhs.uk/resources/?entryid45=75475
4. Recommendations for Terminology, Abbreviations, and Symbols Used in the Prescribing

and Administration of Medicines, Australian Commission on Safety and Quality in Health Care, Darlinghurst. [cited 2010 November 23]. Available from: www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/NIMC_001_NTAS

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Quality Use of Medicines website

For more information regarding high risk medicines and the alert system and access to electronic copies of this Notice and Audit Tool: www.health.vic.gov.au/qum/initiatives/hrm