

A themed review of patient safety incidents involving anti-cancer medicines 1 November 2003 – 30 June 2008

October 2010

Executive Summary

Introduction

The National Patient Safety Agency (NPSA) regularly undertakes themed reviews of patient safety incident reports to better understand risks in a specified area of practice and identify actions and strategies to minimise preventable harm to patients. Patient safety incident reports involving anti-cancer medicines reported between 1 November 2003 and 30 June 2008 were selected for review.

The term 'anti-cancer medicines' has been used throughout to encompass conventional cytotoxic and cytostatic medicines, as well as newer biological treatments such as monoclonal antibodies, so-called 'small molecules', and other targeted therapies.

Patient safety incident reports which described the non-cancer use of anti-cancer medicines, predominantly involving the use of methotrexate to modify the immune response in rheumatology and dermatology, were excluded from the review. The remaining reports were analysed by clinical outcome, stage of the medicines use process, type of incident, and anti-cancer medicine.

Summary of findings

- A total of 4,829 patient safety incident reports involving anti-cancer medicines were reported to the NPSA between 1 November 2003 and 30 June 2008.
- The majority of patient safety incident reports, 94 per cent (4,557), relating to anti-cancer medicines were associated with low harm or no harm to patients.
- Seven patient safety incident reports resulted in validated fatal outcomes, nine resulted in severe harm, and nine resulted in moderate harm outcomes.
- Incident reports involving errors in the administration of anti-cancer medicines were the largest category when analysed by medicine use process (43 per cent).
- The taxanes (docetaxel and paclitaxel) were the most commonly reported group of medicines (9 per cent) and cisplatin was the most commonly reported single medicine (8 per cent), followed by etoposide (8 per cent) and capecitabine (8 per cent). (See Figure 1).
- Reports involving wrong/unclear dose, strength, frequency or quantity of medicine were the most common type of incident (32 per cent). (See Figure 2).

Figure 1 The top ten anti-cancer medicines reported in medication safety incidents

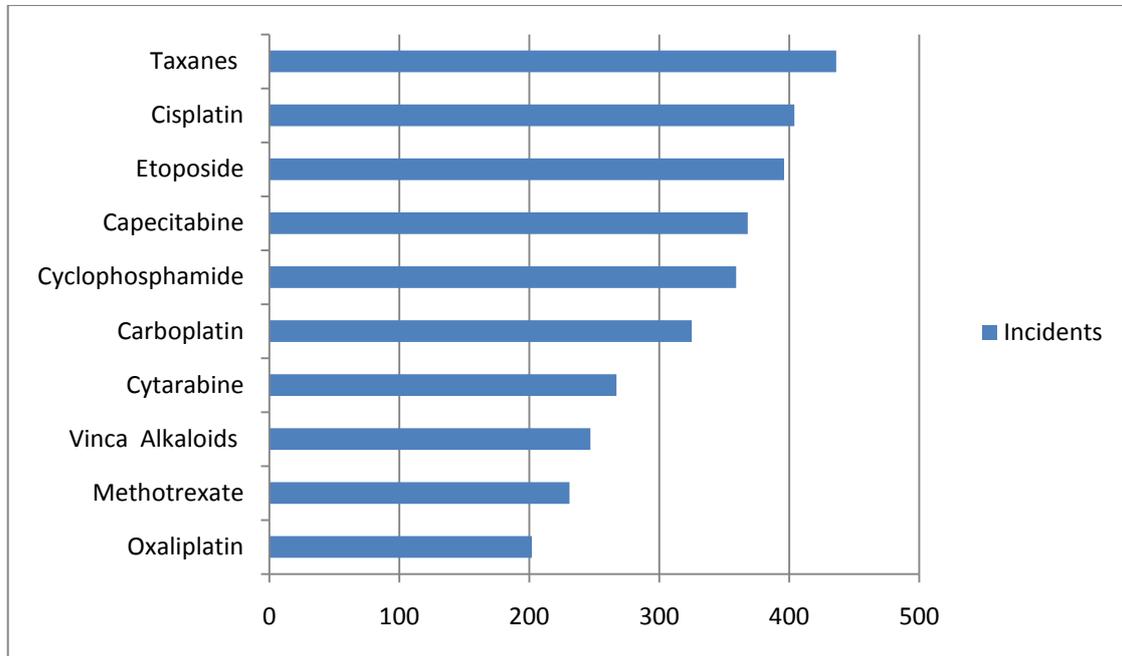
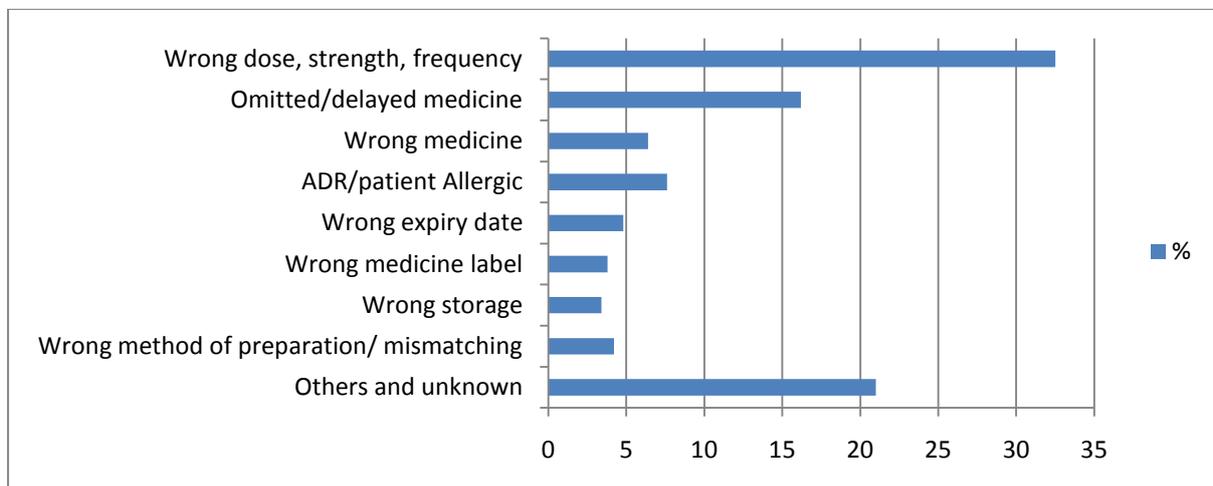


Figure 2 Types of medication safety incidents involving anti-cancer medicines



Recommendations

Following qualitative analysis of these patient safety incident reports, a series of recommendations were developed as suggestions of good practice for local implementation and monitoring in order to improve care and minimise risk in relation to anti-cancer medicines:

- 1) Protocols, prescriptions and all other documentation regarding anti-cancer medicines should be written in a clear and unambiguous manner to minimise misunderstanding and error. All anti-cancer treatment protocols should be risk assessed by organisations producing and using them. Human factors and practical implementation factors that can lead to errors should be considered. Changes should be made to protocols to minimise risks of misinterpretation and reduce the likelihood of failure to follow them in practice. The following specific risks should be addressed:
 - a) Minimise the use of abbreviations of any kind, even if they are considered to be well understood and in common use.
 - b) The sole use of acronyms to identify the intended anti-cancer medicine protocol should be minimised. Where it is essential that acronyms are used, they should always be supported by the full names and doses of the constituent medicines and the intended tumour site. Decisions regarding the creation of acronyms for anti-cancer medicine protocols should be made in the context of those already in widespread use.
 - c) Where the different treatment arms of a clinical trial are associated with different anti-cancer medicine protocols, the naming of the arms should be clear and unambiguous and make explicit reference to the medicines and doses they contain.
 - d) When standard anti-cancer medicine protocols are modified in response to individual patient circumstances the alterations must be explicit and recorded in the patients notes, treatment record and anti-cancer medicine prescription.
 - e) Anti-cancer medicines should be prescribed by generic name and, if appropriate, the specific formulation and its proprietary name. The dose, frequency and duration of treatment should always be written out in full.
 - f) All prescriptions for anti-cancer medicines should specify start and stop dates for the duration of treatment, and the number of days 'off treatment'.
 - g) Prescriptions should always include full directions for use. Prescriptions should never include or be labelled 'To be taken as directed' unless the patient is receiving additional explicit verbal and written information, for example, paediatric oncology patients.
- 2) Healthcare organisations should establish a clear policy on which members of staff are authorised to prescribe and perform other duties with anti-cancer medicines and it should cover all oncology professionals, including doctors, nurses and pharmacists.
- 3) Where anti-cancer medicine protocols are modified or deviate from the standard version routinely used within an organisation, a new prescription should be generated. If this is not possible, any amendments to the standard protocol must be made clearly and unambiguously in all documentation. The term 'modified' is not sufficiently descriptive to be used safely.
- 4) When patients are receiving complicated (in-patient) protocols including supporting treatment, such as mesna or hydration fluids, there needs to be adequate safeguards in place for prescribing, dispensing and administering these medicines alongside the

anti-cancer medicines. Wherever possible, there should only be one anti-cancer medicine prescription containing details of all the medicines the patient requires for each cycle.

- 5) Healthcare organisations should have robust clinical governance systems for setting up anti-cancer medicines onto electronic prescribing systems. These systems should include assigned responsibilities and systems for double-checking and validation.
- 6) Additional precautions are required for oral anti-cancer medicines to ensure that these medicines are used safely. A protocol or patient held treatment plan should be checked every time these medicines are prescribed, dispensed and first administered. In addition, the quantity of tablets and capsules should always be double-checked. Pharmaceutical manufacturers should be encouraged by the NHS to develop clearly distinguishable packs, containing quantities of tablets which more accurately reflect the way their medicines are prescribed and dispensed.
- 7) Patients receiving infusional anti-cancer medicine regulated by a device of any kind should undergo regular monitoring (defined by the organisation), using a monitoring form to ensure that the rate and amount of delivered medicine is as expected.
- 8) It is important that toxicities to anti-cancer medicines are recognised and treated promptly, particularly if the patient presents to a non-oncology setting. Outcomes may be improved by:
 - ensuring patients and carers are well-informed regarding their treatment and possible side effects and where necessary contact specialist staff with training and experience in managing oncology toxicity on the 24 hour number provided to the patient;
 - ensuring that when cancer patients are seen or admitted by non-specialist staff, procedures are in place whereby patients are quickly identified as being or having been on anti-cancer medicines. This is then clearly noted in the clinical record and guidance on management sought from specialist staff with training and experience in managing oncology toxicity;
 - reinforcing that the 24-hour number contact number, issued to patients, can also be used by healthcare staff to obtain advice from cancer specialist staff.
- 9) Tests and investigations relevant to the safe prescribing of anti-cancer medicines should be carried out, verified and documented prior to prescription and administration. In the event of abnormal test results, appropriate action or advice should be taken and any supportive medication should be commenced.