Risks of incorrect dosing of oral anti-cancer medicines

The National Patient Safety Agency (NPSA) is alerting all healthcare staff involved in the use of oral anti-cancer medicines of potentially fatal outcomes if incorrect doses of these medicines are used. These oral anti-cancer medicines are increasingly being used in hospitals and in the community. Risks are increased if non-specialist practitioners prescribe, dispense or administer these oral medicines and bypass the normal safeguards used for injectable anti-cancer medicines.

The NPSA has received reports of three recent deaths and a further 400 patient safety incidents concerning oral anti-cancer medicines between November 2003 and July 2007. Half of these reports concern the wrong dosage, frequency, quantity or duration of oral anti-cancer medicines. It is also likely that there are substantial numbers of unreported incidents.

The number of orally active agents available, particularly the targeted therapies, is likely to increase substantially in the near future. The term oral anti-cancer medicines include those with direct anti-tumour activity, including: bexarotene, busulfan, capcetabine, chlorambucil, cyclophosphamide, estramustine, etoposide, fludarabine, hydroxycarbamide, idarubicin, lomustine, melphalan, mercaptopurine, methotrexate, mitotane, procarbazine, tegafur/uracil, temozolomide, tioguanine, treosulfan and vinorelbine. In addition targeted therapies such as the kinase inhibitors dasatinib, erlotinib, imatinib, sunitinib, and sorafenib are also included. Our use of this term does not include hormonal or anti-hormonal therapy used to treat cancer.

For IMMEDIATE ACTION by the NHS and the independent sector with ACTION COMPLETE by 22 July 2008.

Doctors, nurses, pharmacists and their staff must be made aware that the prescribing, dispensing and administering of oral anti-cancer medicines should be carried out and monitored to the same standard as injected therapy. This requires that:

- Healthcare organisations should prepare local policies and procedures that describe the safe use of these oral medicines.
- Treatment should be initiated by a cancer specialist.
- All oral anti-cancer medicines should be prescribed only in the context of a written protocol and treatment plan.
- Non-specialists who prescribe or administer on-going oral anti-cancer medication should have ready access to appropriate written protocols and treatment plans including guidance on monitoring and treatment of toxicity.
- Staff dispensing oral anti-cancer medicines should be able to confirm that the prescribed dose is appropriate for the patient, and that the patient is aware of the required monitoring arrangements, by having access to information in the written protocol and treatment plan from the hospital where treatment is initiated and advice from a pharmacist with experience in cancer treatment in that hospital.
- Patients should be fully informed and receive verbal and up-to-date written information about their oral anticancer therapy from the initiating hospital. This information should include contact details for specialist advice, which can be shared with non-specialist practitioners. Written information, including details of the intended oral anti-cancer regimen, treatment plan and arrangements for monitoring, taken from the original protocol should be given to the patient. When shared with pharmacists and dispensing staff, this would enable the above dispensing requirements to be satisfied.
- Full use should also be made of NHS cancer centre web sites to provide information for healthcare staff, patients and carers to ensure the safe use of oral anti-cancer medicines.

The above guidance is primarily intended to promote the safe use of the medicines listed to treat cancer. Where the use of these medicines is for non-cancer treatment, a risk assessment should be undertaken and the guidance applied as appropriate.

The NPSA has informed:
All acute sector and primary care NHS organisations, The Independent Sector Healthcare Advisory Services, NHS Cancer Networks, the Medicines and Healthcare products Regulatory Agency, pharmaceutical industry, professional colleges, associations and regulators.

Further Information
Support information on this Rapid Response Report, is available at www.npsa.nhs.uk/health/alerts or contact Professor David Cousins, Head of Safe Medication Practice, NPSA, c/o rrr@npsa.nhs.uk; telephone 020 7927 9356.

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