

Rapid Response Report

NPSA/2009/RRR012

From reporting to learning

19 February 2009

Reducing risk of harm from oral bowel cleansing solutions

Issue

Death and harm from electrolyte abnormalities, dehydration and serious gastro-intestinal problems have been reported following the inappropriate use of oral bowel cleansing solutions (Picolax[®], Citrafleet[®], Fleet Phospho-Soda[®], Klean Prep[®], Moviprep[®]) prior to surgery and/or investigative procedures. Frail and debilitated elderly patients, children and those with contraindications are particularly at risk from these treatments.

Harm from these medicines result from lack of clarity in relation to who is:

- 1) authorising the use of these medicines and is therefore clinically responsible for undertaking clinical checks and explaining their safe use to the patient and;
- 2) authorised to supply these products and is responsible for providing written information about their safe use to the patient or healthcare staff administering these medicines. Currently the supply of these medicines may only involve non-clinical staff (e.g. administrative staff) with inadequate safeguards to ensure safe use.

Evidence of harm

The NPSA has received one report of a death and 218 patient safety incidents involving the use of bowel cleansing solutions up to January 2009. The Medicines and Healthcare products Regulatory Agency (MHRA) has received 11 fatal outcome reports and 44 reports up to 2005. These reports indicate electrolyte imbalance or dehydration due to inappropriate fluid intake or use of these products where there is a clinical contraindication.

For IMMEDIATE ACTION by all NHS sectors and the independent sector where bowel cleansing solutions are used.

Deadline for ACTION COMPLETE is 7 September 2009.

An executive director, nominated by the Chief Executive, working with the lead pharmacist and relevant medical/nursing staff should put arrangements in place to ensure that:

- RRR012/1. A clinical assessment is undertaken by the clinician authorising the surgery or investigative procedure (including GPs using the direct access route) to ensure that there is no contraindication (e.g. clinical condition such as diverticulitis) or risks (e.g. concurrent medication such as diuretics) from the use of a bowel cleansing solution.
- RRR012/2. Use of a bowel cleansing solution is authorised by the clinician at the same time as the surgery or investigative procedure. This may be done by using the same form.
- RRR012/3. The clinician requesting the surgery or procedure and authorising the use of a bowel cleansing solution is responsible for ensuring that an explanation on the safe use of the product is provided to the patient or carer.
- RRR012/4. A safe system exists that involves an authorised clinical professional in the supply of the medicine and written information (including named contact) for each patient. See implementation checklist in supporting information for more details on this.

Further information

Additional information including incident data, clinical information and an implementation checklist to support this Rapid Response Report is available at www.npsa.nhs.uk/rrr. Further queries should be directed to Linda Matthew - Senior Pharmacist, c/o rrr@npsa.nhs.uk; telephone 020 7927 9890.

The NPSA has informed NHS organisations, independent sector, commissions, regulators and relevant professional bodies.