

## Rapid Response Report NPSA/2009/RRR012: Reducing risk of harm from oral bowel cleansing solutions

February 2009

### Supporting Information

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## Background

### Introduction and scope

The NPSA has issued NPSA/2009/RRR012 containing safer practice guidance following reports of death and harm from the inappropriate use of oral bowel cleansing solutions prior to surgery and/or investigative procedures. It covers all age groups, but frail and debilitated elderly patients, children and those with contraindications are particularly at risk from these treatments.

This guidance is relevant to healthcare professionals in all settings involved in the care pathway for the referral and management of patients requiring relevant surgery or investigative procedures or the prescribing, supply or administration of bowel cleansing solutions.

While some scenarios and practices require children to be admitted to hospital to receive bowel cleansing solutions prior to surgery or investigative procedures, some children may be given these medicines to take at home before admission to hospital for the procedure. The NPSA has received a small number of incident reports relating to home administration. None of these reports led to harm on these occasions. However, children are a group particularly at risk of dehydration if fluid balance is not closely monitored.

Organisations should decide on a local dissemination strategy for this Rapid Response Report and supporting information. This should be tailored to local circumstances and arrangements. This might include GPs, consultants (general or other specialist surgeons such as urologists or gynaecologists and also radiologists), junior hospital doctors, community and hospital pharmacists, nurses, pre-admission clinic staff, out patient department nurses, community and bowel specialist nurses, radiographers and administrative managers.

### Products involved include:

Picolax<sup>®</sup>, Citramag<sup>®</sup>, Fleet Phospho-Soda<sup>®</sup>, Klean Prep<sup>®</sup>, Moviprep<sup>®</sup>

### Additional information in this document:

- **Evidence of harm associated with weak systems for the supply and use of bowel cleansing solutions**
- **Clinical information concerning the use of bowel cleansing solutions. (Please refer to the individual manufacturer's full information for each product)**
- **Suggested compliance checklist (Appendix 1).**

## Review of evidence of harm

### Evidence of harm associated with weak systems for the supply and use of bowel cleansing solutions

#### 1.1 Reporting & Learning System (RLS) incident data

The NPSA has been notified of one recent death due to faecal peritonitis associated with intestinal obstruction and caecal perforation where a pre-existing clinical condition contra-indicated the use of a bowel cleansing solution. This incident was notified directly from the office of HM Coroner and is not included in the incident data below.

The NPSA conducted a search for medication patient safety incident reports received via the RLS related to bowel cleansing solutions. There were 218 such reports found in the RLS database, as at 06 January 2009.<sup>1</sup> A number of incidents illustrated the lack of supply controls and safety checks in place.

Interpretation of data from the RLS should be undertaken with caution. As with any voluntary reporting system, the data are subject to bias. A proportion of incidents which occur are not reported, and those which are reported may be incomplete having been reported immediately and before the patient outcome is known.

Data have been produced using a text search for specific word or phrases across the descriptive free text fields in the RLS. Free text fields reported are individual to the reporter, and may contain spelling errors, typographical errors or abbreviations which make it difficult to group similar incidents.

Due to the technical challenges inherent in accounting for all the possible variations in describing a given incident, results from this method should be interpreted carefully. In particular, aggregate figures derived using the method above should not be taken as exactly representative of the data on the RLS.

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<sup>1</sup> The NRLS was established in November 2003 and all NHS organisations were able to report to the NRLS by 1 January 2005. It is important to note the volume of reports received by the NRLS has increased since inception, and as the NRLS is a voluntary reporting system, the data may not be representative of the rates of incidents across England and Wales. Data are based on the date that incident became available for analysis. All incidents since the inception of the NRLS are included.

The following tables provide a breakdown of incidents reported to the RLS.

**Table 1: Incidents involving bowel cleansing solutions by type of medication error**

*Base: All medication incidents involving bowel cleansing medication in the RLS as at 06 January 2009*

<b>Medication Error Category</b>	<b>Number</b>	<b>Per cent</b>
Omitted medicine/ingredient	63	29
Wrong drug/medicine	50	23
Mismatching between patient and medicine	13	6
Wrong/unclear dose or strength/frequency	23	11
Contra-indication to the use of the medicine in relation to drugs or conditions	9	4
Wrong quantity	7	3
Wrong route	6	3
Wrong method of preparation/supply	4	2
Adverse drug reaction (when used as intended)	4	2
Wrong/omitted/passed expiry date	4	2
Wrong/transposed / omitted medicine label	3	1
Wrong/omitted verbal patient directions	1	0
Wrong/omitted patient information leaflet	1	0
Patient allergic to treatment	1	0
Wrong formulation	1	0
Other	25	11
Unknown	2	1
Missing	1	0
<b>Total</b>	<b>218</b>	<b>100</b>

**Table 2: Incidents involving bowel cleansing solutions by stage of medication process**

*Base: All medication incidents involving bowel cleansing medication in the RLS as at 06 January 2009*

<b>Stage of Medication Process</b>	<b>Number</b>	<b>Per cent</b>
Administration/supply of a medicine from a clinical area	122	56
Prescribing	46	21
Preparation of medicines in all locations/dispensing in a pharmacy	29	13
Advice	7	3
Supply or use of over-the-counter (OTC) medicine	3	1
Monitoring/follow-up of medicine use	1	0
Other	9	4
Missing	1	0
<b>Total</b>	<b>218</b>	<b>100</b>

**Table 3: Incidents involving bowel cleansing solutions by degree of harm**

*Base: All medication incidents involving bowel cleansing medication in the RLS as at 06 January 2009*

<b>Degree of Harm</b>	<b>Number</b>	<b>Per cent</b>
No Harm	157	72
Low	46	21
Moderate	14	6
Severe	1	0
<b>Total</b>	<b>218</b>	<b>100</b>

**Table 4: Incidents involving bowel cleansing solutions by location**

*Base: All medication incidents involving bowel cleansing medication in the RLS as at 06 January 2009*

<b>Location</b>	<b>Number</b>	<b>Per cent</b>
General/acute hospital	205	94
Community hospital	5	2
Mental health unit/facility	4	2
Residence/home	2	1
Primary care setting	1	0
Other	1	0
<b>Total</b>	<b>218</b>	<b>100</b>

It should be noted that while Table 4 should represent the location in which the incident occurred, at times the location may incorrectly be reported as the location in which the incident was identified or reported from. Therefore it may not always represent the location where the initial system failure occurred.

## Examples of incident types

### Incident 1

Contra-indication for use

*A patient was admitted pre-operatively for a morning theatre session.*

*The patient had been told in pre-assessment clinic that she was to have Picolax. This was confirmed by the pre-assessment nurse. One sachet of Picolax was given. The nurse then checked the notes and saw that the patient should not have received Picolax due to a history of diverticulitis.*

### Incident 2

Contra-indication for use

*A patient telephoned to query the fact he had been sent Picolax and was anxious as he had had a sigmoid colectomy and ileostomy.*

### Incident 3

Contra-indication for use

*Patient admitted for bowel prep for colonoscopy. I gave a verbal instruction for junior staff to give Clean - Prep not Fleet as high risk of renal failure. Despite this (1) Fleet prescribed (2) Fleet dispensed and given to the patient. Patient developed acute renal failure and remains an inpatient (currently inpatient for 12 days).*

### Incident 4

Wrong dose – procedure re-scheduled

*Patient attended for colonoscopy. On admission patient stated he had only taken one sachet of Picolax as supplied, instead of usual 2 supplied. Discussed with endoscopist - patient to be rebooked due to inadequate bowel preparation.*

### Incident 5

Wrong drug prescribed

*Patient given Picolax (twice) without reason. This was the wrong medicine for the planned operation.*

**Incident 6**

Wrong drug and instructions

*Wrong letter and preparation sent for a flexible sigmoidoscopy instead of for a gastroscopy procedure. Process being changed so that a nurse checks all bowel preparations prior to being sent out.*

**Incident 7**

Managing administration with dysphagia

*Patient has dysphagia and consequently has risk managed feeding (Long term. Puree and Grade 3 thickened fluid.) The patient was drinking Klean Prep, four jugs over 24 hours to prepare bowel for colonoscopy. He had finished 1.5 jugs. Patient was heard by Physio to be very chesty. It was the Physio's impression that the patient had aspirated Klean Prep. The Klean Prep appeared very difficult to thicken with Thick and Easy. Also four jugs is a high volume for a 'Risk Managed Feeding' patient to drink, with the risk of tiring of swallow and aspiration to lungs.*

**Incident 8**

Patient information and management of concurrent clinical conditions and medication

*Patient with known Type 2 diabetes on combined triple oral hypoglycaemic agents and warfarin was admitted from home via A+E with mild dehydration and symptomatic hypoglycaemia causing dizziness and unsteadiness. Due for colonoscopy on 8.7.08. Hypoglycaemia related to bowel prep with background of previously tight glycaemia control. Dose of sulphonylurea not reduced prior to admission. Unclear what advice given to patient regarding dose adjustment or whether Endoscopy team aware of previous low HbA1C (below 7% Sept 07). Clearly documented plan to omit warfarin and presence of diabetes identified on Endoscopy sheet but no record of advice given re other drugs. Patient not entirely clear re his own diabetes management.*

**Incident 9**

Omitted fluids

*Pt under going major bowel surgery the following day - bowel preparation given as prescribed however no intra venous fluid replacement given overnight to aid maintenance of electrolyte balance despite ward staff being aware of pre - op bowel preparation regime.*

**Incident 10**

Omitted fluids

*Patient was admitted to the ward for bowel preparation prior to investigations. Preparation consisted of Picolax and Kleen-Prep. Investigations were endoscopy and colonoscopy. Frail 85 yr old lady, no IV prescribed despite fasting. Unwell with prep - dizzy and hypotensive, IV therefore introduced.*

**Incident 11 – Paediatrics (9 year old)**

Delayed treatment

*Patient who was to undergo colonoscopy was given Picolax at home as prescribed before admission. Patient vomited it out and another dose was given which was also vomited back out. Patient only had one bowel movement and colonoscopy was abandoned. Diagnosis and treatment were delayed.*

## 1.2 Adverse drug reaction data

A review of the Medicines and Healthcare products Regulatory Agency's (MHRA) quantitative data on suspected adverse drug reactions (Drug Analysis Prints, 1963 to 2005) showed a wide range of reported reactions for a variety of bowel cleansing medicines.

Eleven fatal outcomes were reported and associated with the following, cited as potentially single or associated cause. One case was reported for each of the following:

- Small intestine perforation
- Large intestine perforation
- Diverticular perforation
- Intestinal infarction
- Gastro-intestinal obstruction
- Volvulus of bowel
- Peritonitis
- Acute pancreatitis
- Cardiac arrest
- Respiratory failure
- Subarachnoid haemorrhage.

Additionally, there were 44 reports of electrolyte imbalance or dehydration.

The limitations of these data should be noted as further detail and context is not provided.

## 1.3 Professional body notification

In 2001 the Royal College of Radiologists issued a letter to members and fellows following the collapse of a patient due to hypokalaemia when a bowel cleansing solution was taken concurrently with diuretics. This letter reinforced the need for clinical checks for contra-indications and the provision of information to patients.<sup>(1)</sup>

## 1.4 Medical literature

Product information for these preparations cites contra-indications for the use of these types of preparation and side effects which include electrolyte disturbances described as occurring 'less frequently'.<sup>(2)</sup>

The literature cites many studies comparing and contrasting different types of bowel preparation products and side effects are frequently reported.

In 1997 the British Medical Journal (BMJ) printed two letters reporting serious side effects following home use of these medicines.<sup>(3)</sup>

The first of these publications described two separate incidents requiring hospitalisation. The first patient was an 85 year old woman who presented with a score on the Glasgow coma scale of 5/15 and a tonic clonic seizure, having drunk some five litres of water with the sodium picosulphate the previous day (patients receive typed instructions saying "drink plenty of clear fluids").

The second patient was admitted the day after bowel preparation with sodium picosulphate. She presented with diarrhoea and vomiting and was fluid depleted. Her score on the

Glasgow coma scale was 6/15 and she had twitching of her lips. On admission her serum sodium concentration was 121 mmol/l, having been 142 mmol/l two months previously.

The second letter describes a clinical team's investigation following a number of cases of hypotension associated with taking bowel preparation medicines. They describe the haemodynamic effects of these products causing changes to heart rate and postural hypotension. Two of the frailest patients required resuscitation prior to surgery.<sup>(4)</sup>

In 2002 the Australian Adverse Drug Reactions Advisory Committee (ADRAC) published a bulletin advising of 16 reports of adverse drug reactions implicating sodium picosulphate.

Five reports described convulsions associated with hyponatraemia and syncope had been reported with both hyponatraemia and hypokalaemia. There were also single reports of unconsciousness with hyponatraemia, metabolic alkalosis with hypokalaemia and four of syncope and dehydration without documented electrolyte abnormalities. The bulletin advises that low volume sodium phosphate and sodium picosulfate products can cause marked dehydration, hyponatraemia, and other electrolyte abnormalities and associated complications. Infants, the elderly, the frail and those with congestive heart failure or compromised renal function are particularly at risk.<sup>(5)</sup>

## **Evidence on effectiveness and practice**

### **2. Clinical information**

This is a summary of some of the information contained in manufacturers Specification of Product Characteristics (SPC) for bowel cleansing solutions. The SPC for the individual bowel cleansing preparation should be read before prescribing or use and the risks noted and assessed for the individual patient and associated known and/or suspected clinical condition(s).

#### **2.1 Contra-indications for the use of bowel cleansing solutions**

- Use in patients with known or suspected gastrointestinal obstruction or perforation, ileus, gastric retention, acute intestinal or gastric ulceration, toxic colitis or toxic megacolon.
- Severe acute inflammatory disease.
- In patients with severely reduced renal function, accumulation of electrolytes contained in the bowel cleansing medicines may occur in plasma e.g. when using Picolax an accumulation of plasma magnesium may occur. Another preparation should be used in such cases.
- Congestive heart failure.
- Difficulty swallowing.
- Reduced levels of consciousness.
- Hypersensitivity to any of the ingredients.

## 2.2 Special warnings and precautions

- The presence of dehydration should be corrected before use.
- In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment and those at risk of electrolyte imbalance, the physician should consider performing a baseline and post-treatment electrolyte and renal function test.
- Use with caution in patients on drugs that might affect fluid balance e.g. lithium.
- Care should be taken with patients already receiving medicines which may be associated with hypokalaemia (such as diuretics or corticosteroids, or medicines where hypokalaemia is a particular risk i.e. cardiac glycosides).
- The period of bowel cleansing should not exceed 24 hours because longer preparation may increase the risk of water and electrolyte imbalance.
- An inadequate oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard, the elderly, debilitated individuals and patients at risk of hypokalaemia may need particular attention.
- Caution is also advised when bowel preparations are used in patients taking non steroidal anti-inflammatory medicines or medicine known to induce Syndrome of Inappropriate Anti-diuretic Hormone Release (SIADH) e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, antipsychotic drugs and carbamazepine as these medicines may increase the risk of water retention and/or electrolyte imbalance.
- Bowel cleansing medicine may modify the absorption of regularly prescribed oral medication. The absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore be modified during the treatment period.
- Care should also be taken in patients who have recently undergone gastrointestinal surgery.
- Specific information concerning the preparation and dose of specific bowel cleansing products for children are available in the manufacturers SPC. Special attention needs to be taken in communication this information to parents and carers and confirming their understanding.

## 2.3 Overdose

Overdosage with bowel cleansing medicines will lead to profuse diarrhoea. Treatment is by general supportive measures and maintenance of fluid intake.

## 2.4 Information for patients

- Information provided to patients should be clear and unambiguous and tailored to the needs of the individual patient. The specific administration information needs of high risk groups, for example young and elderly patients, should be catered for. It is unlikely that manufacturer's Patient Information Leaflet (PIL) alone will meet the individual needs of all patients. Suggested areas for inclusion include;
- Oral medication should not be taken within one hour of administration of bowel cleansing preparations as it may be flushed from the gastro-intestinal tract and not absorbed.
- No solid food should be eaten for at least two hours before taking bowel cleansing preparations.

- Diarrhoea is an expected outcome of bowel preparation. Please be sure that you have ready access to a toilet at all times following each dose, before the effects wear off.
- Drink plenty of clear fluid, preferably water, throughout the treatment. An indication of maximum and minimum volumes and type of fluid to be taken should be included and tailored to the patient's needs and condition.
- Side effects include nausea, vomiting, bloating, abdominal pain, anal irritation and sleep disturbance.
- Vomiting and severe diarrhoea can lead to fluid loss (dehydration) with dizziness headache and confusion without proper fluid and salt replacement.
- Allergic reactions including rash, itchy, redness and swelling should be reported.
- Appropriate checks should be put in place to ensure that patients and/or their carers fully understand the information and directions provided for the use of these medicines.

## Conclusions and actions for staff

Whilst in the majority of cases the use of bowel cleansing solutions occurs without harm or incident, the NPSA has identified risks and weaknesses in the current system for the supply of bowel cleansing medicines, in particular to vulnerable patients. These weaknesses do not enable the necessary clinical checks to be undertaken and patients are not always receiving sufficient and clear information to assist with safe use.

Staff from the NHS have reported 218 incidents to the RLS and fatalities have been reported via other bodies and agencies.

The Rapid Response Report [NPSA/2009/RRR012] outlines clear actions for the service to minimise risks of using bowel cleansing medicines. This has been issued through the Department of Health's Central Alert System (CAS) in England and directly to organisations in Wales. It applies to all organisations in the NHS and independent sector where bowel cleansing medicines are used.

The deadline date for actions complete is six months after the date of issue. This implementation period takes into account the potential for cross healthcare sector/boundary discussions and agreements to be secured.

In England, compliance with the recommendations should be entered on CAS by CAS liaison officers. To assist organisations in implementing these actions, a checklist is given in Appendix 1 which can be adapted for local use. These actions should help to ensure the safety of patients using bowel cleansing medicines by standardising practice and clarifying roles and responsibilities.

## References

1. Royal College of Radiologists, Adverse reactions to Picolax. Letter 20<sup>th</sup> March 2001
2. British National Formulary. BMJ Publishing, RPS Publishing. 54, (September 2007)
3. Lewis M et al. Patient should be warned not to drink too much or too little fluid. *BMJ* 1997; 314: 74 (4 January)
4. Hanning CD. Give a simultaneous infusion of saline in frail patients. *BMJ* 1997; 314: 74 (4 January)
5. ADRAC. Electrolyte disturbances with sodium picosulphate bowel cleansing products. *Aust Adv Drug React Bull* 2002; 21: 1

## Appendix: Suggested compliance checklist

Note that actions apply to all organisations where bowel cleansing medicines are used. Primary care trusts and local health boards have responsibilities to ensure that the contents of the Rapid Response Report are communicated to relevant independent contractors, who should be aware of the risks and take the necessary action outlined in this RRR.

No	Recommendation	Action	Compliance Y/N
RRR012/1	A clinical assessment is undertaken by the clinician ordering the surgical or investigative procedure (including GPs using the direct access route) to ensure that there is no contra-indication or special precaution for the use of a bowel cleansing solution.	Review arrangements for the prescribing and supply of bowel cleansing solutions to ensure that roles and responsibilities are clear, agreed and documented, in particular, across healthcare boundaries Update local policy and procedures Date approved by clinical governance group(s)	
RRR012/2	Use of a bowel cleansing solution is authorised by the clinician at the same time as the surgical or investigative procedure is ordered. This may be done by using the same form.	Review arrangements for the prescribing and supply of bowel cleansing solutions to ensure that roles and responsibilities are clear, agreed and documented, in particular, across healthcare boundaries Update local policy and procedures Update investigation request form to enable clinical authorisation of bowel cleansing solution Date approved by clinical governance group(s)	
RRR012/3	The clinician requesting the surgical or investigative procedure, and authorising the use of the bowel cleansing solution, is responsible for ensuring that an explanation on the safe use of the medicine is provided to the patient or carer.	Review arrangements for the prescribing and supply of bowel cleansing solutions to ensure that roles and responsibilities are clear, agreed and documented, in particular, across healthcare boundaries and in relation to information provided to the patient/carer. Ensure that information is available to assist with explaining safe use and taking account of individual patient factors. Update local policy and procedures Date approved by clinical governance group(s)	

RRR012/4	A safe system exists that involves an authorised clinical professional in the supply of the bowel cleansing solution and written information is available for each patient.	Review arrangements for the prescribing and supply of bowel cleansing solutions to ensure that roles and responsibilities are clear, agreed and documented, in particular, across healthcare boundaries Update local policy and procedures Provide written information materials for patients Date approved by clinical governance group(s)	
RRR012/4a	Ensure storage and supply comply with medicines regulations.	Where applicable, review local arrangements for storage (mainly applicable to the acute sector) and ensure that arrangements for supply comply with medicines regulations. Update local policy and procedures Date approved by clinical governance group(s)	
<b>Written information should be made available to patients, carers and healthcare professionals and incorporate the following:</b>			
RRR012/4b	Information is available for the patient, carer or healthcare staff to enable them to assess whether it is still safe to use the bowel cleansing solution just prior to administration (i.e. in case of delay between prescribing and administration during which the patient's condition may have changed/deteriorated)	Update/provide written information for use by the patient/carer at home or healthcare staff enabling an assessment of the patient's condition just prior to use Date approved by clinical governance group(s)	
RRR012/4c	Information concerning the safe preparation and administration of the medicine.	Update/provide written information Date approved by clinical governance group(s)	
RRR012/4d	Contact information to obtain the advice of a clinical professional if needed.	Update/provide written information Date approved by clinical governance group(s)	
<b>Other implementation considerations:</b>			
A	Communication to health care staff about the new arrangements for bowel cleansing solutions	Communication plan Date plan approved by clinical governance group(s)	
B	Evaluation plan – how the organisation will confirm that safer systems for the use of bowel cleansing solutions have been implemented. This will involve; - Checking staff and patient awareness - Audit of procedures in practice - Review of incidents where the safe system has not operated	Evaluation plan Date plan approved by clinical governance group(s) Review date set	