

Patient safety alert

19



Alert

28 March 2007

Immediate action

Action

Update

Information request

Ref: NPSA/2007/19

Promoting safer measurement and administration of liquid medicines via oral and other enteral routes

The National Patient Safety Agency (NPSA) is advising healthcare organisations on how the design of medical devices and the methods used to measure and administer oral liquid medicines* can improve patient safety.

A review of data from the NPSA's National Reporting and Learning System (NRLS) shows 33 patient safety incidents involving intravenous administration of oral liquid medicines between 1 January 2005 and 31 May 2006.

Incorrect intravenous administration of oral liquid medicines has resulted in three reported deaths between 2001 and 2004,¹⁻³ and there are reports of four incidents of harm or near misses between 1997 and 2004.⁴⁻⁷ This risk has been recognised in the Department of Health report *Building a safer NHS for patients: Improving medication safety*⁸ and in other publications worldwide.⁹⁻¹³

Action for the NHS and the independent sector

1 Design, supply and use of oral/enteral syringes

- only use labelled oral/enteral syringes that cannot be connected to intravenous catheters or ports to measure and administer oral liquid medicines;
- do not use intravenous syringes to measure and administer oral liquid medicines;
- make sure stocks of oral/enteral syringes are available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe;
- when patients or carers need to administer oral liquid medicines with a syringe, supply them with oral or enteral syringes.

2 Design, supply and use of enteral feeding systems

- enteral feeding systems should not contain ports that can be connected to intravenous syringes or that have end connectors that can be connected to intravenous or other parenteral lines;
- enteral feeding systems should be labelled to indicate the route of administration;
- three-way taps and syringe tip adaptors should not be used in enteral feeding systems because connection design safeguards can be bypassed.

* The term 'oral liquid medicine' will be used throughout the document to mean liquid medicine, including soluble tablets once dissolved and feeds or flushes to be administered by oral and other enteral routes, including rectal administration. Flushes include water, sodium chloride 0.9% and air.

For response by:

- All NHS and independent sector organisations in England and Wales

For action by:

- The chief pharmacist/pharmaceutical advisor should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/risk manager

The following groups must also be involved in implementation:

- Clinical governance leads and risk managers
- Medical staff
- Nursing staff
- Nutritional nurse specialists
- Speech and language therapists, physiotherapists, dieticians
- General practitioners
- Patient advice and liaison service

- Procurement managers

The NPSA has informed:

- Chief executives of acute trusts, primary care organisations, ambulance trusts, mental health trusts and local health boards in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)

- Business Services Centre (Wales)
- Medicines and Healthcare products Regulatory Agency
- NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Prescription Pricing Authority
- Royal colleges and societies
- British Dietetic Association
- NHS Direct
- Relevant patient organisations and community health councils in Wales



3 Organisational procedures, training and audit

- medicines and enteral feeding policies and procedures should identify and manage the risk of administering oral liquid medicines by the wrong route;
- these procedures should be part of the organisation's training and competency assessment programmes;
- annual medicines management audits should include a review of the measurement and administration of oral liquid medicines to ensure compliance with local policies and procedures.

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 2 July 2007

Deadline (action complete): 30 September 2007

Use of oral/enteral syringes in all clinical areas

All other recommendations: 31 March 2008

Further information about SABS can be found at:

www.info.doh.gov.uk/sar2/cmopatie.nsf

Further information on the action points

1 Design, supply and use of oral/enteral syringes

General design issues

An appropriate oral/enteral syringe should be used to measure oral liquid medicines if a medicine spoon or graduated measure cannot be used. These syringes should not be compatible with intravenous or other parenteral devices. By 30 September 2007, stocks of oral/enteral syringes should be available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe.

From 30 September 2007, patients and carers required to administer oral liquid medicines with a syringe should only be given oral/enteral syringes.

Healthcare staff should be informed that intravenous syringes, with male luer slip or male luer lock tips (see the glossary on page 10 for definitions) for measuring and administering oral liquid medicines, increase the risk of wrong route errors.

The medical devices industry produce oral/enteral syringes in a range of sizes with tips that are not compatible with intravenous or other parenteral devices. These syringes are clearly labelled for oral/enteral use and may have coloured plungers or barrels to further help identification. Press-in bottle adaptors that facilitate the use of these syringes with medicine bottles are also available.

While as part of the provision of pharmaceutical services, dispensers in primary care currently only have to issue the patient with a 5ml oral enteral syringe when a spoon is not suitable, because more complex medication regimes are now being administered at home, the NPSA recommends that primary care dispensers should be in a position to issue a range of oral/enteral syringes. As a minimum, a 1ml, 5ml or 10ml syringe should be supplied depending on the dose prescribed.

Oral/enteral syringes are supplied as either sterile or non-sterile devices. They may be for single use or for single patient use depending on the manufacturer's guidance and local medicine policies.



Catheter tip syringes are not sufficiently accurate to measure or administer small volumes of oral medicines.

Labelling of oral/enteral syringes

All oral/enteral syringes should be clearly labelled to aid selection and use. These devices must be clearly labelled 'Oral' and/or 'Enteral' in a large font size. If a manufacturer has not supplied syringes with this label, it is the healthcare practitioner's responsibility to label the device with this information.

Judicious use of colour and design can help healthcare staff identify oral/enteral syringes and prevent oral medicines being drawn up into intravenous syringes by mistake. Some manufacturers supply oral/enteral syringes with purple coloured plungers or syringe barrels to help differentiate them from intravenous syringes.

The NPSA recommends that standard-setting organisations develop a standard for the labelling, colour and design of oral/enteral syringes.

All oral/enteral syringes containing oral liquid medicines must be labelled with the name and strength of the medicine, the patient's name, and the date and time it was prepared by the person who has prepared the syringe, unless preparation and administration is one uninterrupted process and the unlabelled syringe does not leave the hands of the person who has prepared it. Only one unlabelled syringe should be handled at any one time.

2 Design, supply and use of enteral feeding systems

Enteral feeding systems should not contain ports that can be connected to intravenous syringes or have end connectors that can be connected to intravenous or other parenteral lines.

Ports on nasogastric and enteral feeding catheters through which liquid medicines are to be administered, or which may be used for aspiration, must be male luer, catheter tip or other non-female luer in design. Nasogastric and enteral feeding catheters must not be able to be connected to intravenous syringes or administration sets. This is in compliance with European Standard EN 1615:2000.¹⁴

Enteral administration and extension sets must not contain any in-line female luer administration ports or connect to the patient using a male luer terminal connector.

The presence of female luer ports requires the use of intravenous (male luer-tipped) syringes which can be attached to intravenous and other parenteral lines. Similarly, the presence of a male luer terminal connector on enteral administration or extension sets makes it possible for the enteral line to be connected to intravenous and other parenteral lines.

Currently, the medical devices industry supplies enteral administration and extension sets with a range of connectors. Male luer tips to fit female luer ports on enteral feeding tubes is a standard intravenous or parenteral connector combination. These should **not** be used for administering oral or enteral liquids, and the NPSA recommends healthcare organisations do not purchase them.

Recommended connector combinations

To reduce the risk of wrong route errors, the NPSA recommends that healthcare organisations should only purchase enteral feeding devices with the combinations below:

- female luer connector to fit male luer ports on enteral feeding tubes (reverse luer connector combination);
- catheter tip connector to fit catheter tip ports on enteral feeding tubes;
- non-luer (non-standard connector that does not fit any non-flexible port).



These recommendations do not prevent the medical devices industry from developing new connector combinations that reduce the risk of wrong route error, either in-house or in response to any future European Standard connector design.

The NPSA has held meetings with representatives from the medical devices industry and informed them of its recommendations. It is anticipated that device manufacturers will incorporate these safer connector combination designs into their product ranges within 12 months of this patient safety alert, if they have not done so already.

Risk assessment

Healthcare organisations should undertake a risk assessment of the enteral feeding system devices they currently use. This should identify which enteral feeding system devices and practices do not meet the NPSA recommendations. The NPSA also recommends healthcare organisations develop an action plan for managing identified risks and only purchase the enteral feeding system devices with connector combinations recommended above. From 31 March 2008, NHS purchasing organisations will be able to provide information on these devices.

In the interim, where devices that do not have the recommended connector combinations are still in use, organisations should acknowledge the risk of continuing to use these devices in their risk registers, implement local risk management strategies and seek to purchase safer devices as soon as they become available.

Three-way taps

Avoid using three-way taps in enteral systems as these devices introduce additional risks:

- they have additional ports which enable wrong route errors;
- there are additional risks of infection;
- the system is more complex because multiple lines may be attached to the same system.

If using three-way taps in enteral systems is unavoidable, healthcare organisations should acknowledge this risk in their risk register and implement local risk management strategies to minimise these risks.

Using adaptors to convert oral/enteral syringe connectors

Converting connectors on oral/enteral syringes so that they may connect to intravenous lines and other parenteral devices increases the risk of wrong route errors.

Some healthcare organisations may find it necessary to continue to use adaptors for a short period while safe connector ports are fitted to enteral feeding devices. These risks should be acknowledged in the risk register and local risk management strategies to minimise these risks should be implemented.

The NPSA recommends that from 31 March 2008, adaptors that enable oral/enteral syringes to fit luer ports should not be used.

Devices designed for uses other than enteral

Such devices should only be used for the administration of oral liquid medicines in exceptional circumstances following a risk assessment of the individual clinical circumstances.



If devices, such as urinary catheters and intravenous administration sets are used, and also when intravenous syringes have to be used (to prepare oral medicine doses from intravenous medicines products, or used in a syringe driver pump to administer oral medicines), there is a potential for confusion, and possible connection with other lines in the same patient. The Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance on the misuse and off-label use of medical devices.¹⁵ The MHRA recommends that when a healthcare organisation or health professional judges that there is no alternative but to use a medical device off-label or to modify the device, they should carry out and document a full risk assessment and consider the ethical and legal implications. The patient should also be informed during the consent procedure and a note made in the patient's records.

Labelling of enteral devices

All enteral system devices should be clearly labelled to aid selection and use. These devices must be clearly labelled 'Enteral' in a large font size. If a manufacturer does not supply their device labelled in this way, it is the responsibility of the healthcare practitioner to label the device with this information.

Judicious use of colour and design will aid differentiation between devices intended to be used for the enteral route and other routes, and help prevent oral medicines being administered by the wrong route. For example, some manufacturers supply enteral catheters, and administration and extension sets with purple connectors or line colour.

The NPSA recommends that standard-setting organisations develop a standard for the labelling, colour and design of enteral devices.

3 Organisational procedures, training and audit

The risks of wrong route errors with oral liquid medicines should be identified in healthcare organisations' medicines management and enteral feeding policies and procedures. The importance of using safe devices, connector combinations and methods should be emphasised.

Training programmes for staff who measure and administer oral liquid medicines and use enteral feeding systems should emphasise the need to use safe devices and follow agreed policies and procedures. Senior staff should supervise newly trained staff to ensure they have the necessary work competences to undertake their duties safely and effectively. There should be additional training for staff when changes are made to procedures or devices.

Additional guidance for NHS organisations

Guidance on administering medicines via enteral feeding tubes, including a patient guide, GP guide and a practical guide has been published by the British Association for Parenteral and Enteral Nutrition (BAPEN) and is available at:

www.bapen.org.uk

A handbook providing more detailed information about administering medicines via enteral feeding tubes has recently been published by the British Pharmaceutical Nutrition Group.¹⁶

In 2005, the NPSA published a patient safety alert aimed at reducing the harm caused by misplaced naso- and orogastric feeding tubes. This is available at:

www.npsa.nhs.uk/health/alerts

As part of their annual medicines management audit, NHS organisations should audit the preparation of oral liquid medicines to ensure practice adheres to NPSA recommendations and local procedures. Audit results should be viewed alongside local patient safety incident data relating to the use of oral liquid medicines. A template audit



Cost of implementing NPSA recommendations

Oral/enteral syringes currently cost about 10 pence more than an equivalent intravenous syringe. Changing to oral/enteral syringes could cost a large hospital up to £10,000 per year. However, many healthcare organisations are already using oral/enteral syringes in paediatric areas. This cost does not take into account the fact that many of the non-sterile oral/enteral syringes can be washed and reused. It is anticipated that as larger volumes of oral/enteral syringes are purchased, the unit cost will fall.

It is anticipated that large hospitals could save up to £5,000 a year if they stop using three-way taps and syringe tip adapters in enteral feeding systems.

None of the other action points are expected to have significant additional costs.

Background information

Oral liquid medicines are often administered to babies, young children and adults who have impaired ability to swallow tablets and capsules. These medicines may be measured and administered using a 5ml medicine spoon, a graduated measure, or a graduated oral or enteral syringe. They may be administered by mouth or, when indicated, via a licensed feeding tube.

If intravenous syringes are used to measure and administer oral liquid medicines, there is an increased risk of wrong route errors by connecting to intravenous or other parenteral lines.

The design of some enteral feeding systems includes the use of luer ports (see the glossary on page 10 for definitions) originally designed for the administration of medicines by the intravenous route. European Standard EN 1615:2000 recommends that connectors (but not ports) on enteral feeding systems should be incompatible with other medical device connectors (used for intravenous and other parenteral routes). If luer ports are included, the feeding system requires the use of a compatible intravenous syringe for oral liquid medicines and this increases the risk of wrong route errors.

NHS organisations may not have identified the risks of wrong route errors with oral liquid medicines and they should have formal written procedures and training on administering these safely.

Table 1: Clinical outcomes of NRLS wrong route incidents where oral liquid medicines were administered by the intravenous route, reported to the NRLS between 1 January 2005 and 31 May 2006

Clinical outcome ¹⁰	No. reports
Death	1
Severe harm (permanent harm)	2
Moderate harm (significant, but not permanent harm, requiring an increase in treatment)	2
Low harm (temporary harm, requiring extra observation or minor treatment)	8
No harm	20
Total	33

Although the majority of incidents reported to the NRLS resulted in low or no harm, they all involved intravenous administration of oral liquid medicines and feeds, and provided evidence that supported the development and implementation of the recommendations in this alert



Examples of errors from NRLS reports:

- 1 "The patient became unwell and unresponsive after (oral) dipyridamole had been given via a central intravenous (PICC) line. Observations were unattainable and suction was given. The medical team was fast bleeped as the patient was obviously deteriorating. The patient died whilst doctors were present." *Outcome: death*
- 2 "Patient given enteral feed down Hickman line in error. Patient had severe back pain, reduced oxygen concentration in blood, increased pulse as fat embolus entered subclavian vein leading to the heart and lungs." *Outcome: severe harm*
- 3 "Post lung transplant patient complaining of sudden onset of flushing and heavy sensation in chest. Found that oral cyclosporin was given IV via central line." *Outcome: moderate harm*
- 4 "A nurse had prepared omeprazole syrup to give via a nasogastric (NG) tube. Whilst the nurse was identifying the patient's NG tube she was distracted. She rushed this procedure so she could go and assist her colleague. As soon as the omeprazole was given the nurse realised that this drug had been given IV via a central line, instead of NG. The drug was immediately withdrawn. The patient dropped their blood pressure. Medical staff were called immediately. A small amount of adrenaline was given to the patient to correct the hypotension. The patient recovered quickly, and did not incur any long term effects." *Outcome: low harm*
- 5 "Gave approx 15mls of diclofenac dissolved in drinking water into femoral line that was intended for NG tube administration." *Outcome: no harm*
- 6 "4ml of furosemide syrup 10mg/ml was drawn up in an IV syringe for NG administration. The nurse who had drawn this up was away from the patient and a second nurse administered the syringe contents intravenously." *Outcome: low harm*
- 7 "I accidentally gave some spironolactone via the central line. I realised my mistake after injecting approximately 2ml." *Outcome: no harm*
- 8 "Gave patient oral morphine intravenously instead of prescribed oral route." *Outcome: no harm*
- 9 "Child received phenytoin oral suspension by incorrect route – was administered via a Hickman line instead of the gastrostomy tube." *Outcome: no harm*
- 10 "20 mls dispersible paracetamol given to patient in error via central line when prescribed via NG." *Outcome: no harm*
- 11 "Oral morphine 100mg in 5mls dispensed into 5ml syringe for accurate measure, by mistake administered intravenously." *Outcome: low harm*

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Further details

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For more information on the NPSA, visit www.npsa.nhs.uk

For more information about how you can improve patient safety, visit
www.saferhealthcare.org.uk – one stop for knowledge and innovation for
safer healthcare.

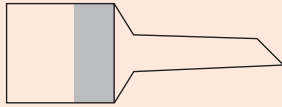
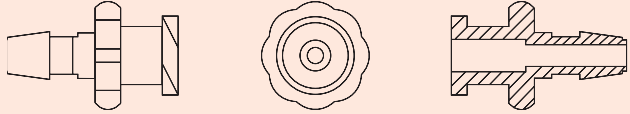
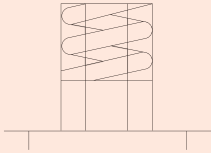


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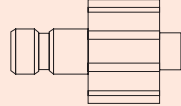
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Glossary

Term	Definition
Barrel (of syringe)	The hollow cylinder of a syringe in which fluids are measured.
Catheter	A tubular flexible device for removing fluids from, or delivering fluids to, a body cavity.
Catheter tip	
Dead space	The volume of fluid remaining in the tip of a syringe after the plunger of the syringe has been fully depressed into the barrel.
Enteral	Nutrition or medicine given directly into the gastrointestinal tract.
Female luer	Describes the shape and size of the port which connects with a male luer connector. The standard shape of devices designed to access the vascular system: 
Intravenous	Into, or within, a vein or veins.
Luer	Conical fittings with a 6% taper used for syringes, needles and certain other medical equipment (BS EN 20594-1:1994, ISO 594/1:1986).
Luer lock	Conical fittings with a 6% taper used for syringes, needles and certain other medical equipment which include a lock fitting. 



Male luer	<p>Describes the shape and size of the nozzle (tip) of a syringe that connects to a female luer port.</p>  <p>The standard shape of the tip of an intravenous syringe.</p>
Nasogastric tube	<p>A flexible plastic tube passing into the stomach through the nostril and nasopharynx.</p>
Oral	<p>Taken directly through the mouth.</p>
Parenteral	<p>Not through the gastrointestinal tract. By injection through some other route, e.g. intravenous, subcutaneous, intramuscular.</p>
Plunger	<p>The movable part of the syringe which is pushed down the barrel to expel its contents or pulled up within the barrel to fill the syringe.</p>
Syringe	<p>A device for injecting or withdrawing fluids.</p>



A patient safety alert requires prompt action to address high risk safety problems.

This patient safety alert was written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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