NATIONAL PATIENT SAFETY AGENCY
DRAFT PATIENT SAFETY ALERT

Safer Use of Injectable Medicines In Near-Patient Areas

Wide Stake Holder Consultation
January – March 2006

The NPSA is undertaking a wide stake holder consultation on recommendations intended improve the safe use of injectable medicines in near patient areas.

We would be very grateful to receive your comments and suggestions concerning this draft using the attached response form by Friday 31st March 2006.

The NPSA plans to issue final recommendations to improve the safer use of injectable medicines in the NHS in England and Wales later in 2006.

Please send your responses to:

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Consultation commenced on 30th January 2006

We have also established a discussion group concerning injectable medicines in the medication practice section at www.saferhealthcare.org.uk/ihi/forums. You are invited *to* post your comments and join in the discussion on this NPSA initiative.

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Introduction

Risks associated with the use of injectable medicines in near-patient areas have been recognised for some time. In 1976 The Breckenridge Report[1] made recommendations about safeguards for the addition of medicines to intravenous infusions. In 2001 the Audit commission found evidence that high-risk injectable medicines were commonly being prepared in near-patient areas in English hospitals[2]. Regrettably, in today's NHS, when injectable medicines are used to a greater extent than ever before, there are few additional safeguards operating. NHS Scotland issued a Good Practice Statement for the Preparation of Injections in near-patient areas in 2002[3]. There are no similar publications for the NHS in England and Wales, although in 2003 the Medical Devices Agency, (now part of the MHRA), included guidance on the use of infusion pumps and systems in a Device Bulletin [(11)]

There have been case reports of deaths and harm associated with the unsafe use of injectable medicines[4-5]. There is research evidence that the incidence of errors observed in the prescribing, preparation and administration of injectable medicines is higher than for other forms of medicines [6-9]. In one study at least one error occurred in 49% of intravenous medicine doses prepared on hospital wards; 1% were judged to be potentially severe errors, and 29% potentially moderate errors[7]. The NPSA receives many reports each month concerned with errors with injectable medicines. These incidents are not only caused by individual acts but also latent system risks that allow unsafe practice[10].Overall the safe handling of injectable medicines has been found to have a low priority in healthcare organisations[10].

The objective of this patient safety alert is to introduce a co-ordinated approach to ensure that injectable medicines are used safely in healthcare organisations. This will be achieved by raising awareness of the risks of using injectable medicines, providing a quick and easy to use risk assessment tool and aid organisations prioritise actions that can help minimise latent system risks.

Main risks

1) Non-availability to clinical staff at the point of use, of essential information about injectable medicines. Such information may not be included in the manufacturer's pack or in commonly available reference sources.
2) Incomplete and ambiguous prescriptions which don't include complete details of the solution to be used to dilute the injectable medicine (diluent), final volume, final concentration or intended rate of administration.
3) Presentations of injectable medicines that may require complex calculation, dilution and handling procedures before the medicine can be administered
4) Selection of the wrong medicine or diluent.
5) Use of a medicine or diluent or infusion after its expiry time and date.
6) Calculation errors made during prescription, preparation, administration of the medicine, leading to administration of the wrong dose and/or at the wrong concentration or rate.

7) Incompatibility between diluent, infusion, other medicines and administration devices.
8) Administration to the wrong patient.
9) Administration by the wrong route.
10) Unsafe handling or poor aseptic (non-touch) technique leading to contamination of the injection and harm to or infection of the patient.
11) Health and safety risks to the operator or environment.
12) Variable levels of knowledge, training and competence amongst health care practitioners

The NPSA has worked with the National Implementation Board for Modernisation of NHS Medicines Manufacturing and Preparation and a multidisciplinary advisory group of healthcare professionals/organisations to develop the following recommendations to promote safe practice with injectable medicines.

Action for the NHS

NHS acute trusts, primary care organisations and local health boards in England and Wales should take the following steps:

1) Undertake a risk assessment of the injectable medicines procedures and products used in their organisation to identify high risks and develop an action plan to minimise them. The NPSA has developed a risk assessment tool to support this process.
2) Ensure that there are up-to-date written protocols and procedures for the prescribing, preparation and administration of injectable medicines by all healthcare professionals in all near-patient areas where injectable medicines are used. The NPSA has developed a set of multidisciplinary practice standards and standard operating procedures on which to base local protocols and procedure.
3) Ensure the availability of essential information for the safe use of injectable medicines to staff at the point of use, in all near-patient areas where injectable medicines are used.
4) Ensure that medicine infusions are monitored throughout administration and consider the introduction and the use of a checklist or monitoring form, if one is not already in use.
5) Implement “purchasing for safety” policies to promote procurement of products with inherent safety features in preference to those that pose patient safety risks.
6) Implement a programme of training to ensure that staff are competent to prescribe and use injectable medicines safely.
7) Audit practice against standards and report on compliance with protocols and procedures each year. The report should be communicated to Trusts’ Clinical Governance and Drugs and Therapeutics Committees each year and should be reviewed by external organisations as part of the performance management process.

For response by:

- All NHS trusts and local health boards in England and Wales

For action by:

- Medical Director
- Directors of Nursing
- Chief Pharmacists/pharmaceutical advisers

The following groups must also be involved in implementation:

- Clinical governance leads and risk managers
- Medical staff
- Clinical pharmacy staff
- Nursing staff
- Radiography staff
- Podiatry staff
- Other allied heathcare staff that prescribe, prepare and administer injectable medicines
- General Practitioners
- Patient advice and liaison service staff in England
- 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)
- Healthcare Commission
- Healthcare Inspectorate Wales
- Medicines and Healthcare Products Regulatory Agency
- NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Royal colleges and societies
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- Independent Healthcare Forum
- Relevant education providers

Action for the Safety Alert Broadcast System (SABS)
Proposed date for issue of Alert :
Deadline (action underway) :
Deadline (Action complete):
Further information about SABS can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

Further information on the action points

1) Risk assessment

The NPSA has developed a risk assessment tool to help to identify high-risk injectable medicine products and practices within healthcare organisations and to suggest methods to help minimise these risks (Appendix 1)

Regular risk assessment of injectable medicines should be undertaken by a pharmacist and senior clinical practitioner in all near-patient areas. The results should be reported to the organisation's Clinical Governance and Drugs and Therapeutics Committee's and a priioritised action plan should be developed to minimise the identified risks.

Measures to reduce risk are likely to include:

- Elimination/minimisation of the use of concentrated injectables requiring complex calculations and dilution before administration by substituting ready-to-use/ready-to-administer products that are safer.
- Elimination/minimisation of the use of "open system" methods for preparation and administration (i.e. those which necessitate injectable medicines being emptied into and/or withdrawn from open containers.)
- Use of double checking systems e.g. by a second practitioner and/or by use of "smart" infusion pumps and similar technologies.

2) Written protocols and procedures for use of injectable medicines

Healthcare organisations should ensure that there are written protocols and procedures for prescribing, preparation and administration of injectable medicines by all healthcare professionals in all relevant areas. It is essential that all procedures are clearly documented, reflect local circumstances and describe safe practice which all practitioners can reasonably be expected to achieve. Patient safety incidents commonly result when staff do not follow written procedures due to lack of awareness, insufficient knowledge or because they do not agree with them and routinely violate them

To assist organisations to develop local protocols and procedures, the NPSA has produced

- a Multidisciplinary Practice Standard (Appendix 2) which lists the core principles of safe practice and
- an exemplar Standard Operating Procedure for prescribing, preparation & administration of Injectable Medicines available in the medication practice section at www.saferhealthcare.org.uk/ihi/forums

3) Provision of essential information

Injectable medicine products commonly either do not have a package insert with essential information or the information is insufficient to fully meet the needs of health professionals.

Full technical information is not available in commonly used medicines references such as the British National Formulary.

NHS organisations need to provide users with technical information concerning the following for all injectable medicines products used in near-patient areas:

Reconstitution	Manufacturer's recommended solution (diluent) for dilution and reconstitution of a freeze dried powder
Concentration of final solution	Recommended concentration and volume for administration, stating maximum concentration where applicable
Example calculations	Examples of dose/preparation and rate of administration calculations
Dilution/flush solutions	Information concerning physical/chemical compatibility with diluents and infusion fluids
Stability in solution	Recommended expiry for the prepared final injection or infusion
Administration rate	For bolus administration and infusion for all routes of administration
Compatibility information (for commonly used mixtures in specialist areas only)	Mixed in the same syringe/infusion, in administration tubing and at Y-sites and three way taps where mixing occurs
Special handling information	If special precautions and handling methods have to be used during preparation and administration e.g. protect from light
Specialist Technical information (where relevant)	pH, osmolarity, sodium content, Displacement values,

Some information of this type is available for use nationally but more is required.

The NPSA are in discussion with the UK Intravenous Therapy Guide, UK Medicines Information Service and the National Electronic Library for Health and other stakeholders about the national development of a NHS Injectable Medicines Guide that can be used by healthcare organisations to assist them to provide this information to health professionals working in near-patient areas.

4) Infusion monitoring forms

Medicine infusions need to be monitored throughout administration to ensure that are being administered at the correct rate, that cannulae have not become blocked or disconnected, that infusion pumps and devices are working as intended and that the patient is responding to the infusion therapy as intended.

Organisations should consider the use of an infusion monitoring checklist or form to identify the components of safe practice and facilitate documentation of compliance .

5) Implement a purchasing for safety policy

Following risk assessment, each organisation will have identified a list of high-risk products. Where possible, this list of products should be rationalised by multidisciplinary collaboration.

Licensed ready-to-administer or ready-to-use products should be procured and supplied when available. If a licensed product of this type is not available the use of unlicensed products should be considered. Unlicensed ready to use/ready-to-administer products that cannot be prepared in the hospital pharmacy department should be sourced from NHS manufacturing units or commercial specials manufacturers.

6) Training and competence assessment

NHS organisations must ensure that staff who prescribe, prepare and administer injectable medicines have the necessary work competences to undertake their duties safely.

A competence is an expectation of work performance. Skills for Health (SfH) has been commissioned by DH to develop healthcare competencies for all sectors of the NHS (www.skillsforhealth.org.uk).

Using the SfH format, the NPSA is developing four work competences templates to assist local organisations define the required knowledge and skills:

- Prescribing injectable medicines.
- Preparing injectable medicines.
- Administering injectable medicines.
- Monitoring administration

Details of these competences will be available in the medication practice section at www.saferhealthcare.org.uk/ihi/forums during the first quarter of 2006. The NPSA recommends that Skills for Health, working with other stakeholders, incorporates and develops other work competences to complete the competency framework for the use of injectable medicines in the NHS.

In order to assist practitioners assess their current level of competence, the NPSA is developing a competency assessment template that can be adapted and used by local organisations

As part of the training it should be reinforced to practitioners that patient safety incidents with injectable medicines must be reported and reviewed through the organisation's usual risk management procedures.

7) Annual injectable medicines report

Organisations should produce an injectable medicines report each year that summarises risk assessment results, incident reports, compliance with NPSA recommendations and in-year actions. It should describe an action plan to improve poorly performing aspects of the system. The report should be communicated to Clinical Governance and Drugs and Therapeutics Committees each year. This information should also be used as part of the performance management process by external organisations.

Trusts should develop a selection of Key Performance Indicators to aid monitoring. Suggested examples of indicators are

- A documented annual risk assessment.
- An annual record of injectable medicine-related incident reports.
- Evidence of review of reports at appropriate committee's.
- The number of ready-to-use and ready-to-administer product lines used in the organisation.
- The number of identified high-risk (PSR Red) items prepared in clinical areas and in pharmacy

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