Safe Medication Practice Report 2007
Council of Europe

Professor David Cousins
Head of Safe Medication Practice
National Patient Safety Agency
National Health Service
London
Patient Safety

Patient safety is the freedom from accidental injury in health care
Background To Report

• Medication errors are the most common single preventable cause of adverse events in Europe
• Group tasked to review medication safety and to prepare recommendations to specifically prevent adverse events caused by medication errors in European health care.
• Multidisciplinary healthcare professionals
• Representatives from European Countries
Objectives of Report

Provide information to:

• enhance awareness of medication errors across the European countries and recognition as an important system-based public health issue;

• provide guidance for reducing medication errors and preventable adverse drug events

• help European health authorities, governments and regulatory agencies, pharmaceutical companies, organisations and professional societies, health professionals and patients selecting top safety practices for implementation both at
Report Overview

- Introduction: provides the scope of the report
- Chapter I: explores how to prevent errors by learning from medication errors
- Chapter II: outlines how to measure and evaluate medication safety
- Chapter III: explains how the design of medicinal products used in Europe can be developed to improve the in use-safety of medicinal products
- Chapter IV: describes methods for improving safe medication practices
- Chapter V: explores how medicine information practices contribute to medication safety
### Table 1: Main results of national multi-centre studies on adverse effects

<table>
<thead>
<tr>
<th>Studies</th>
<th>Year of data collection</th>
<th>No of patients</th>
<th>Stays with at least one serious adverse event</th>
<th>Adverse drug events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvard Medical Practice Study (HMPS)</td>
<td>1984</td>
<td>30,195</td>
<td>3.7%</td>
<td>19.4%</td>
</tr>
<tr>
<td>Quality Australian Health Care Study (QAHCS)</td>
<td>1992</td>
<td>14,179</td>
<td>16.6%</td>
<td>10.8%</td>
</tr>
<tr>
<td>Thomas et al. (UCMPS)</td>
<td>1992</td>
<td>14,732</td>
<td>2.9%</td>
<td>19.3%</td>
</tr>
<tr>
<td>Schioler et al. (Denmark)</td>
<td>1998</td>
<td>1,097</td>
<td>9.0%</td>
<td></td>
</tr>
<tr>
<td>Davis et al. (New Zealand)</td>
<td>1998</td>
<td>6,579</td>
<td>12.9%</td>
<td>15.4%</td>
</tr>
<tr>
<td>Vincent et al. (United Kingdom)</td>
<td>1999</td>
<td>1,014</td>
<td>10.8%</td>
<td></td>
</tr>
<tr>
<td>Canadian Adverse Events Study (CAES)</td>
<td>2000</td>
<td>3,745</td>
<td>7.5%</td>
<td>23.6%</td>
</tr>
<tr>
<td>French Adverse Event Study (ENEIS)</td>
<td>2004</td>
<td>8,574</td>
<td>6.6%</td>
<td>19.5%</td>
</tr>
<tr>
<td>- prospective study in hospitalised</td>
<td></td>
<td></td>
<td></td>
<td>31.0%</td>
</tr>
<tr>
<td>- cause of hospitalisation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spanish Adverse Event Study (ENEAS)</td>
<td>2005</td>
<td>5,624</td>
<td>9.3%</td>
<td>37.4%</td>
</tr>
</tbody>
</table>
Table 2: The incidence of medication errors in Europe

<table>
<thead>
<tr>
<th>Stage in the medication use system</th>
<th>Ambulatory care</th>
<th>Hospital settings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing</td>
<td>7.5%</td>
<td>0.3 - 9.1%</td>
<td>% of medication orders</td>
</tr>
<tr>
<td>Dispensing</td>
<td>0.08%</td>
<td>1.6 - 2.1%</td>
<td></td>
</tr>
<tr>
<td>Administration</td>
<td>Not available</td>
<td>49.3%</td>
<td>Direct observation studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.1 - 47.5%</td>
<td>- intravenous medicine doses prepared on wards</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.4 - 8.6%</td>
<td>- traditional floor stock or ward stock systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.2 - 9.1%</td>
<td>- ward stock system with original prescription and daily ward visits by pharmacists</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.5%</td>
<td>- patient prescription distribution systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.4 - 9.7%</td>
<td>- unit dose drug distribution manual system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- unit dose drug distribution computerised or automated systems</td>
</tr>
</tbody>
</table>
Table 3: The cost of preventable adverse drug events in European countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Additional hospital cost per preventable adverse drug event</th>
<th>Estimate of the national annual cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>€ 3 000</td>
<td>€ 400 million</td>
</tr>
<tr>
<td>Germany</td>
<td>€ 3 700</td>
<td>€ 706 million (72% preventable)</td>
</tr>
<tr>
<td>United-Kingdom</td>
<td></td>
<td>€ 636 million (38% preventable)</td>
</tr>
</tbody>
</table>
Figure 2: MERS Co-ordination at supranational European level

Nationally recognised focal point for safe medication practices

World Alliance for Patient Safety

WHO International Non-proprietary Names Programme

World Health Organization
NPSA Patient Safety Observatory Report
Medication Safety Incidents

- National Centres for Safe Medication Practices should publish annual reports to identify
- risks and methods that have been used effectively to manage these risks.
- The information should be collated at European level and should be used to inform the external assessment
- of health care organisations.
NRLS Medication Incidents – Reported Degree of Harm

- No Harm: 83.2%
- Low: 12.6%
- Moderate: 4.0%
- Death: 0.1%
- Severe: 0.1%
NRLS Medication Incidents – Care Setting

- Acute: 78%
- Community Services: 9%
- Mental Health: 7%
- Community Pharmacy: 3%
- GP's: 1%
- Other: 2%
NRLS Medication Incidents – Stage

- Administration: 59%
- Dispensing/Preparation: 18%
- Prescribing: 16%
- Other: 7%
The 10 most common types of medication error reported to the NRLS

- Wrong dose, strength, frequency
- Omitted medicine / ingredient
- Wrong drug / medicine
- Other
- Wrong quantity
- Mismatching between patient and medicine
- Wrong / transposed / omitted medicine label
- Patient allergic to treatment
- Wrong storage
- Wrong / omitted / passed expiry date

Percentage
European Medicines Regulations

• Current European medicines regulations concerning naming, packaging and labelling for pharmaceutical products provide inadequate safeguards for patients.

• Medication errors frequently occur in Europe because of sound-alike or look-alike drug names, similarities in packaging and labelling appearance and unclear, ambiguous or incomplete label information.
The Importance Of Human Factors

• There is little recognition of the importance of the human factor principles in selection and design of drug names, labels and packages in order to minimise the potential for error and enhance medication safety.

• The current design for labelling and packaging prioritise industry concerns, such as “trade dress”, instead of considering the context where the pharmaceutical product has to be used. It is not patient-centred, but, rather, relies on an assumption of perfect performance by healthcare professionals and by patients.
Recommendations for machine readable codes on medicinal products

It is recommended that:

• EU medicines regulations should be updated to include design features for packaging and labelling of medicine products that take incorporate human factors and promote safe use in practice.

• Include a requirement, that packaging and labelling be subject to human factor assessment and user testing to be undertaken by the manufacturers.
Recommendations for machine readable codes on medicinal products

- Continuing the current non-standardised and unregulated use of machine readable codes on medicinal products is likely to increase risks for patients in Europe.
- These codes are expected to be used more frequently in clinical practice in the future. Inaccurate, confusing or unreadable codes or codes not included in health care databases may pose risks.
- Machine readable codes need to be standardised and considered together with other labelling information in the course of the marketing authorisation procedure of medicinal products in order to ensure patient safety and to prevent new risks.
Recommendations for machine readable codes on medicinal products

• European medicine regulations should include requirements for machine readable codes.
• As an important element, the medicine regulations should require that pharmaceutical companies provide unit dose medicines with a bar code.
Recommendations for machine readable codes on medicinal products

- With a view to full benefit for patient safety by this technology, it is recommended that the following changes are made to European medicines regulations:

- All medicinal products marketed in Europe should have an EAN-13 code bar containing the GTIN on the primary medicine container as a minimum requirement with an implementation period of two years;
Recommendations for machine readable codes on medicinal products

- have a data matrix bar code or RFID chip on both the primary container and unit dose with an implementation period of five years.
- The GTIN, batch number and expiry date should be encoded; include a unique serial number if the medicine is at risk of being counterfeit.
EFPIA Supply Chain Integrity Initiative

- Use of data matrix bar codes
- Enabling anti-counterfeiting and other patient safety safeguards
Ensuring safer practice with Repevax® and Revaxis® vaccines

There have been a number of reported patient safety incidents and near misses involving Repevax® and Revaxis® vaccines, where staff have mistakenly given the wrong vaccine. This is due to similar product names, labelling and packaging.

New packaging is due shortly. This notice highlights this change to healthcare professionals, and provides a guide to how they can minimise risk in the short-term.

Action for the NHS

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

1. Ensure procedures are in place to check the correct vaccine has been selected for the individual patient concerned on each and every administration.

2. Raise awareness of the proposed changes to the packaging with all staff involved in childhood immunisations (see page 3). This may include displaying pictures of the product packaging in all locations where the vaccine is stored or used. To reduce the chances of staff selecting the wrong vaccine, where possible staff should use up stocks in the original packaging style first.

3. Review procedures for risk assessment and management of new vaccine products introduced locally, and strengthen procedures where necessary.

4. Continue to report any patient safety incidents (see page 4).

For responses to:

- NHS acute trusts including foundation trusts, primary care organisations and local health boards in England and Wales
- Action by:
  - Directors of public health in England and Wales, primary care
  - Chief pharmacists in England and Wales, secondary care
- The NPSA recommends that RPS organisations disseminate this information to:
  - Pharmacists in community pharmacies
  - Medical, nursing and pharmaceutical clinical governance leads
  - Risk managers
  - Directors of nursing
  - Professional leads for school nursing
  - District immunisation co-ordinators
  - Procurement managers
  - Communication leads
  - Patient Advice and Liaison Services (PALS) in England
  - Claims managers
  - Therapists
  - Patient and public involvement leads

The NPSA has informed:

- Chief executives of acute trusts, primary care organisations and local health boards in England and Wales
- Regional directors of public health of strategic health authority regions and regional offices (Wales)
- Healthcare Commission
- Healthcare Inspectorate Wales
- NHSA
- Wales Health Supplies
- NHS Direct
- Regulatory and professional organisations
- Community Pharmacists and Health Visitors Association (CPHVA)
- Medicines and Healthcare products
- Primary and Community Care Pharmacy Networks
- Monitor
- Quality Improvement and quality improvement groups in Scotland and Northern Ireland
- Independent Healthcare Forum
- Health Protection Agency
- Commission for Social Care Inspection
- Community Health Councils (CHCs) in Wales
Patient Safety Incident Involving Vaccine Products

REPEVAX®
Diphtheria, Tetanus, Pertussis (Acellular Component) and Poliomyelitis (Inactivated) Vaccine, adjuvanted Suspension for injection
1 single dose 0.5 millilitre prefilled syringe
Suspension for intramuscular injection
Aventis Pasteur MSD

REVAXis®
Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed)
Suspension for injection
1 single dose 0.5 millilitre prefilled syringe
FOR INTRAMUSCULAR INJECTION ONLY
Aventis Pasteur MSD
Safer practice notice

Ensuring safer practice with high dose ampoules of diamorphine and morphine

There have been a number of reports of deaths and harm due to the administration of high dose (30mg or greater) diamorphine or morphine injections to patients who had not previously received doses of opiates. This notice promotes safe practice with these medicines, it is not intended to prevent appropriate clinical use in patients who need them.

Risks
The major risks are:

• Packaging of different strengths of diamorphine and morphine ampoules look the same; the outer carton and ampoule labelling are poorly differentiated; and 5mg, 10mg, 15mg, 20mg and 30mg products have similar appearances.

• Higher strength ampoules of diamorphine and morphine (30mg, for example) stored alongside lower strength products (10mg, for example) in clinical areas in both primary and secondary care.

• Insufficient therapeutic training and understanding on the part of the healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine injections.

Actions for the NHS

1 Risk assess and have procedures for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections.

2 Review therapeutic guidelines for the use of diamorphine and morphine injectable products for patients requiring acute care, including post-administration observation of patients who have not previously received doses of opiates.

3 Update information concerning the safe use of diamorphine and morphine injectable products as part of an ongoing programme of training for healthcare staff on medication practice.

4 Ensure that naloxone injection, an antidote to opiate-induced respiratory depression, is available in all clinical locations where diamorphine and morphine injections are stored or administered.
Look-a-like packaging for Diamorphine
Patient Safety Incident Involving Diamorphine Ampoules
Use Blank Space To Emphasise Critical Information
Critical Information In The Same Field of Vision
On At Least Three Non-Opposing Faces
Use Colours To Differentiation to Highlight Information
Allocate Space for a Dispensing Label
Recently Re-Designed Packaging
Recently Re-Designed Packaging
Design for Safety
Labelling and Packaging Guidelines for Injectable Medicines
Name and Strength

Proprietary Name
Generic Name
For i.v. use
5ml ampoules
5mg/ml

Proprietary Name
Generic Name
For i.v. use
25mg/5ml
Ampoule Design
Vial Design

Proprietary name
Emulsion for injection or infusion
Generic name.
Each 1ml contains 10mg of Generic Name.
Each 500mg vial contains 500mg Generic Name. Also contains:
- soybean oil refined, triglycerides medium
- bottled egg phosphatide, glycerol, oleic acid
- hydroxide and water for injections.
To be used
- intravenously, subcutaneously, intramuscularly.
Batch and Expiry

Batch: 645981
Exp: 08/03/31

Batch: 645981
Use before: Mar 08
Infusion Design
Highlight Route of Administration
Bar Codes
Peelable Ampoule/Vial Labels
Differentiating Injectable Medicine

Adrenaline Injection BP

1 ml
1:1000
Adrenaline 0.1% w/v (1 mg Adrenaline in 1 ml)

Use as directed by a physician
Keep out of the reach of children
Store in a cool place and protect from light
A sterile solution for I.M., S.C. and diluted for
I.V. use in emergencies
Inactive ingredients:
Sodium Metabisulphite BP C1% w/v
Sodium Chloride BP 0.9% w/v and Water for injections to 100% w/v
P Number: 1502/0024
PL Holder

Atropine Sulphate Injection

1 ml
600 mcg in 1 ml

Each 1 ml contains Atropine Sulphate BP 0.06% w/v
in Water For Injections
A sterile solution for I.M., I.V. or S.C. injection
Use as directed by a physician
Keep out of the reach of children
Protect from light and store at less than 25 C
Inactive ingredients: Water For Injections BP to 100% w/v
PL Number: 1502/0018R
PL Holder
Design for patient safety
A guide to the design of dispensed medicines

Edition 1
2007
Dispensing Labels

28 Medicine Name 200mg tablets
Take ONE tablet THREE times a day
Warning avoid alcoholic drink
Take with or after food
Take regularly and complete the course
Mrs A. Patient (Reg.2) 12 Jul 2007

For advice 020 7089 2627
Keep out of the sight and reach of children
A. Pharmacy 123 Pharmacy Street, Town, AB1 C34

35mm

70mm
Room For Dispensing Labels
The Use of Bar Codes
Labelling Small Containers
Summary

- Safe medication practice is an important public health issue in Europe
- Current European medicines regulations concerning naming, packaging and labelling for pharmaceutical products provide inadequate safeguards for patients
- The Council of Europe Safe Medication Practice Report Recommends changes in European Regulation to require the use of a GTIN, batch number and expiry date and a unique serial number (where appropriate) on outer packs and unit of use packaging in five years.
More information

www.npsa.nhs.uk