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Translating Data Into Medication Safety

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Finding the clues and solving the problem

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Collecting the evidence

National Reporting
And Learning System

Pharmacovigilence data
Research & audit data
Professional indemnity
The media
Coroners
Professionals
Patients and carers

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Definitions

Patient safety is the freedom from accidental injury in healthcare

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare – errors of commission and omission

A hazard is the potential to cause harm

a risk is the likelyhood of harm – usually qualified by details of circumstance and severity of harm

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National reporting and learning system (NRLS)

National database established in 2003

Incident data transferred from individual health provider organisation databases

This data is then analysed to identify hazards, risks and opportunities to improve the safety of patient care

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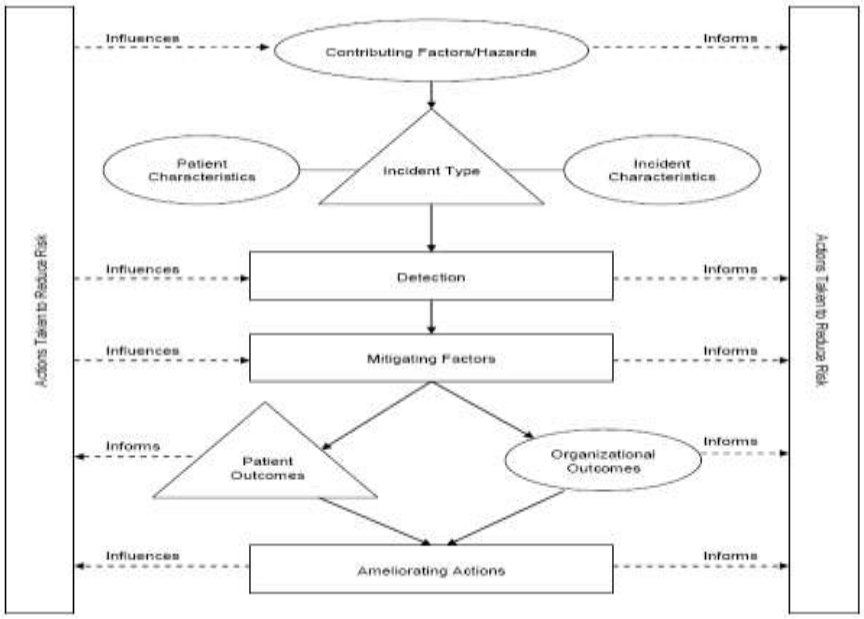
WHO International Classification for Patient Safety



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An improving safety culture

- Where staff are aware of the importance of patient safety and incident reporting and are willing to report incidents within a fair blame culture

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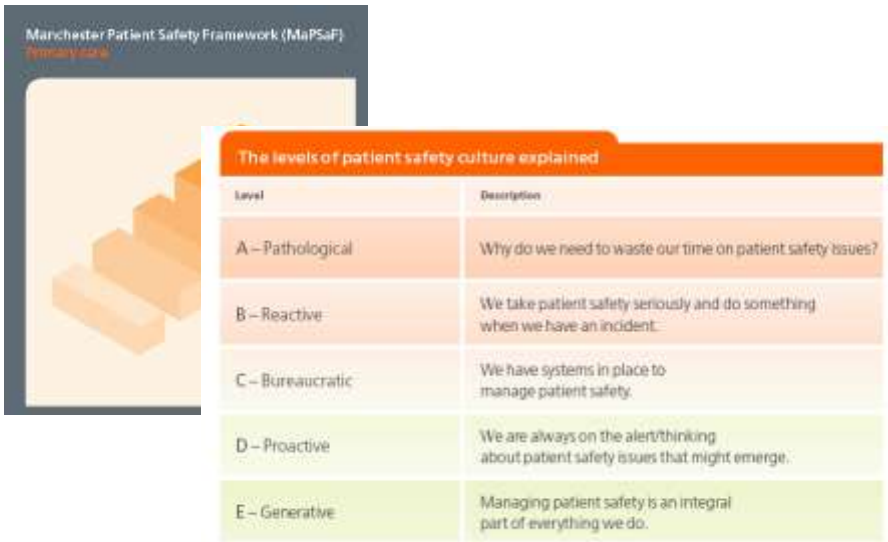
Culture



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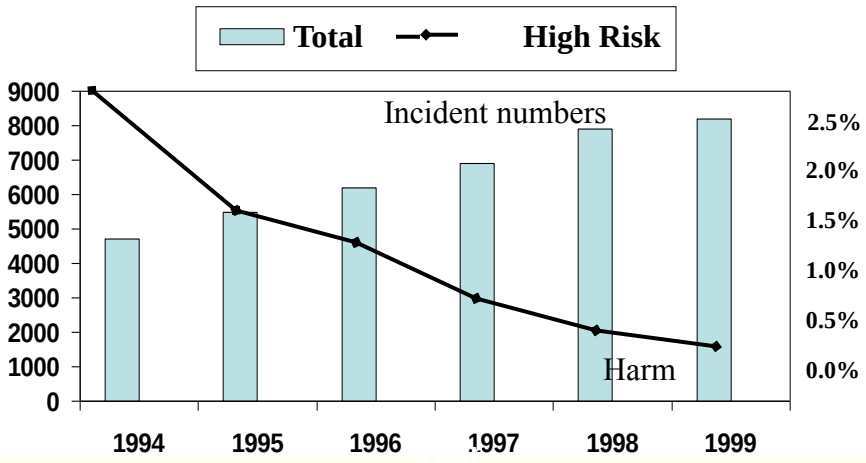
Air Safety Reports: Volume & Risk Reduction



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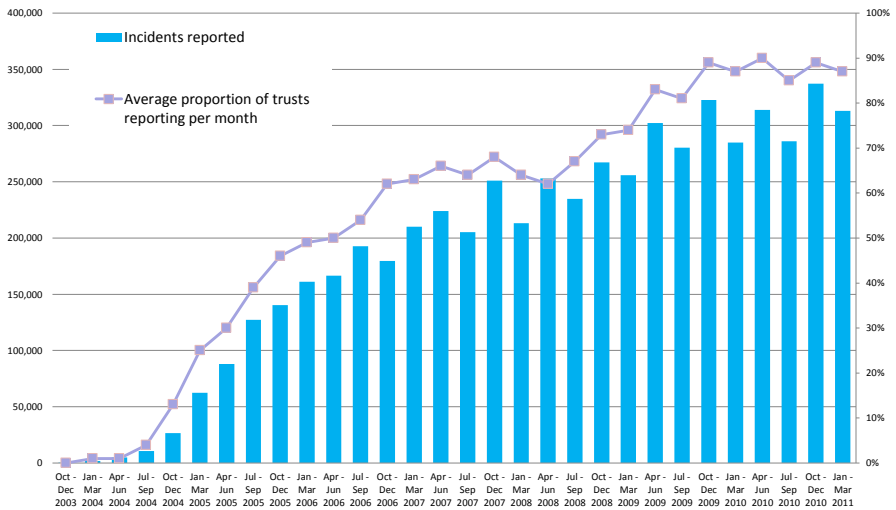
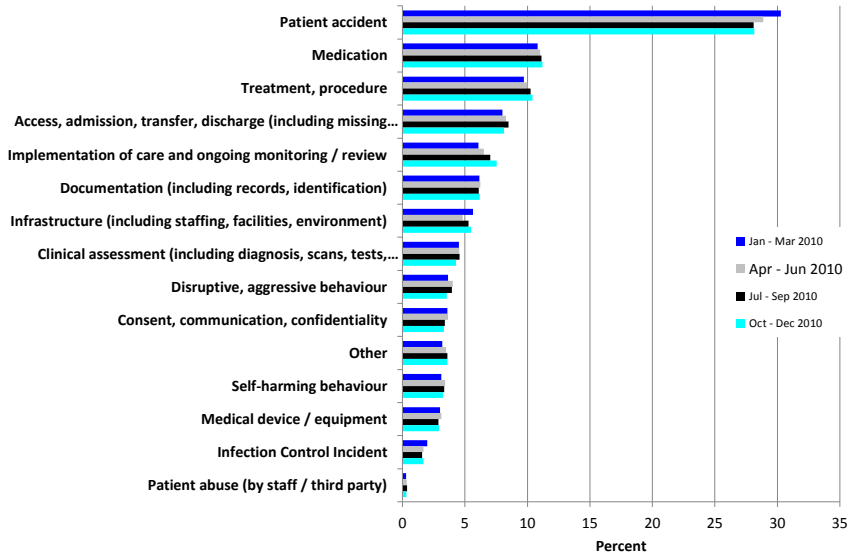
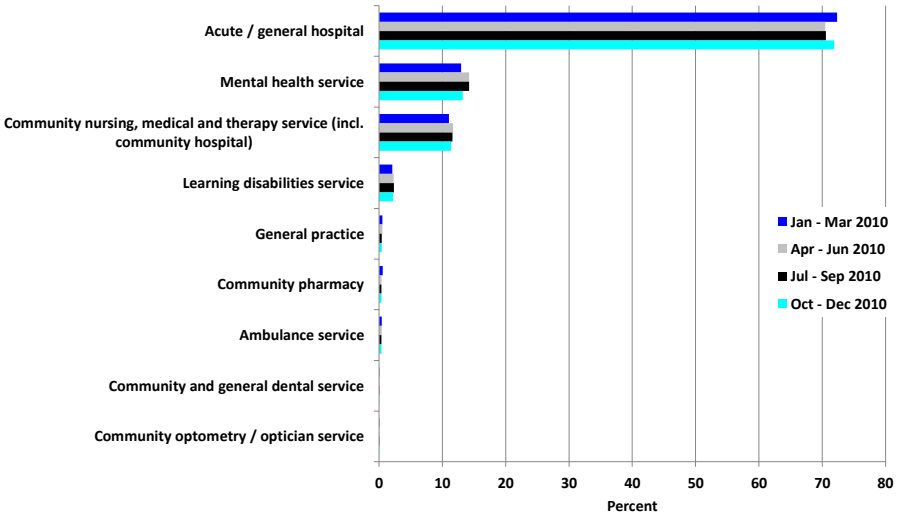
Incidents reported from Oct 2003 - Mar 2011, and average proportion of Organisations submitting per month



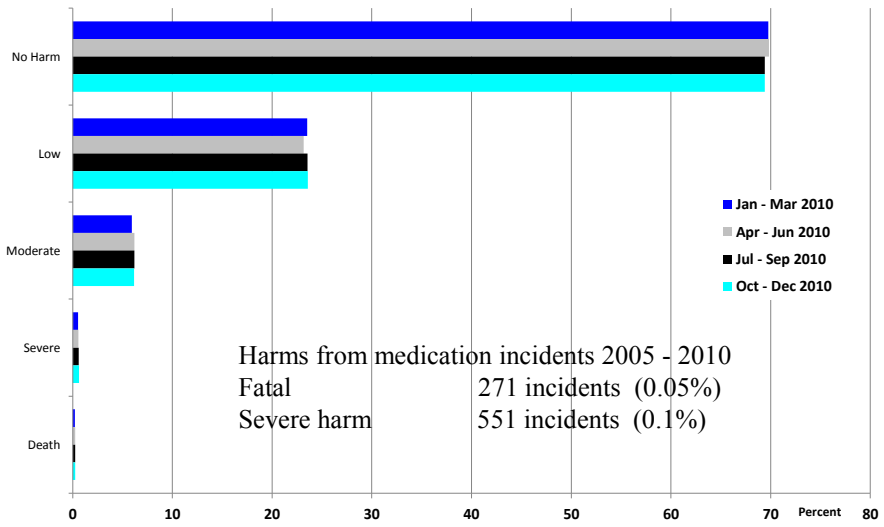
Proportion of incidents by incident type and quarter, January 2010 - December 2010



Proportion of incidents by care setting and quarter, January 2010 - December 2010



Degree of harm by quarter, January 2010 - December 2010



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Incidents numbers 2005 - 2010

- All incidents 5,438,000
- Medication incidents 526,379 (11%)

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Analysis methods

Clinical outcome
Medication process step
Medication incident type
Medicine/therapeutic group
Root cause analysis
Failure modes and effects
Human factors
System and product design

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Clinical outcome
Medication incidents 2005 - 2010

Actual clinical outcome	Incidents*	Percent of medication incidents
Death	271	0.05
Severe	551	0.10
Moderate	17421	3.31
Low	68578	13.03
No harm	439318	83.46
N/A	240	0.05
Total	526379	100.00

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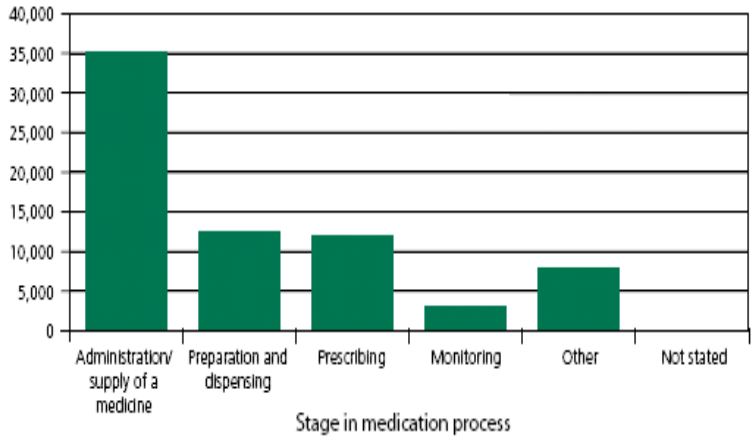
Chart 1 Medication incidents by stage of medication process – all care settings, 2007



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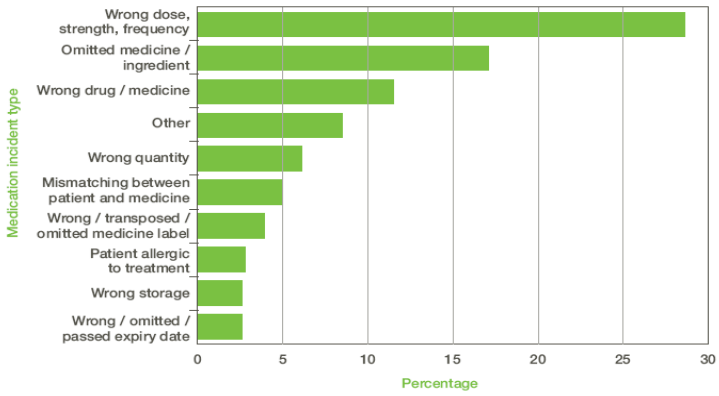
Types of medication safety incidents



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Top therapeutic groups reported In NRLS medication incidents

Therapeutic group	Confirmed degree of harm		Total (% of total)
	Severe harm	Death	
Opiates	5	7	12 (13%)
Anticoagulants	8	2	10 (10.9%)
Anaesthetics	3	2	5 (5.4%)
Insulin	6	2	8 (8.7%)
Antibiotics	2	3	5 (5.4%)
Chemotherapy	0	4	4 (4.3%)
Infusion fluids	1	2	3 (3.3%)
Antipsychotics	2	0	2 (2.2%)
Other	27	16	43 (46.7%)
Total	54	38	92 (100%)

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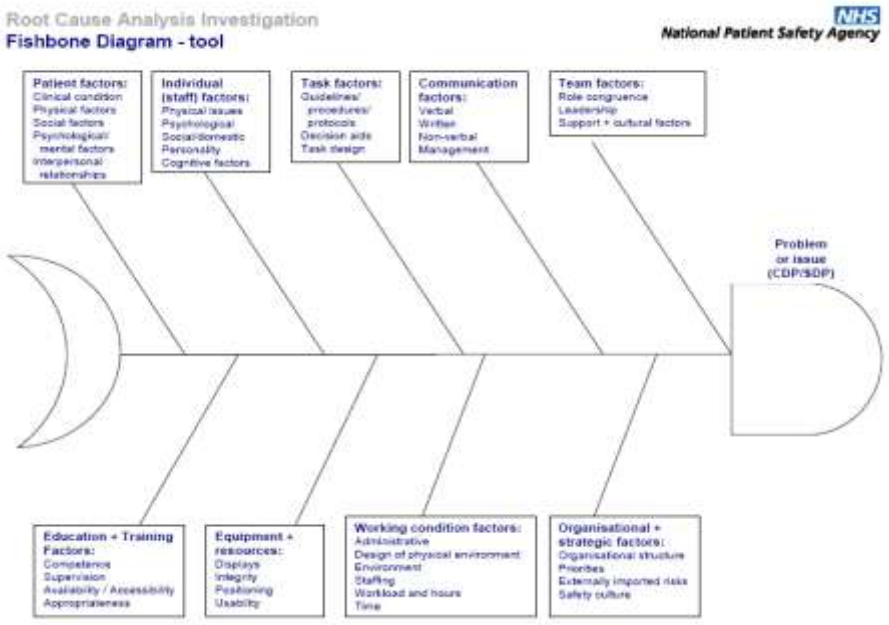
Root cause analysis



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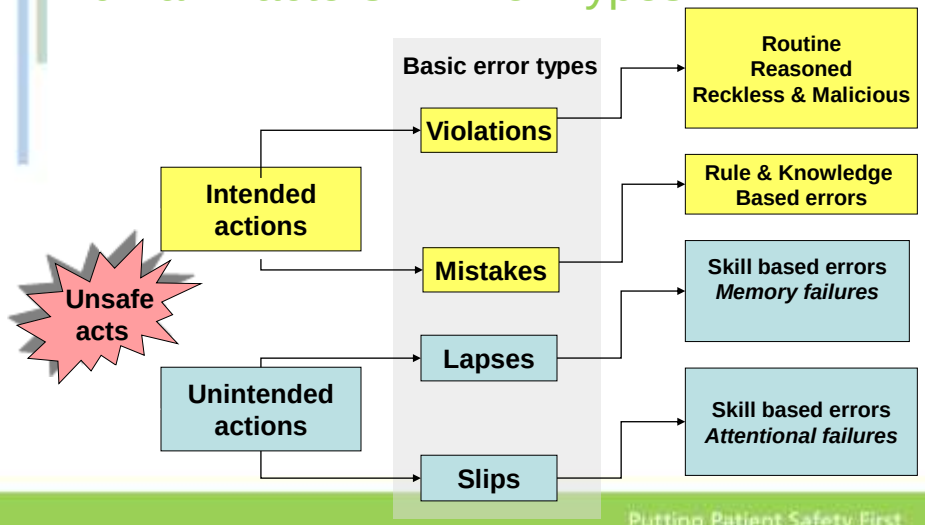
Human Factors – Error Types



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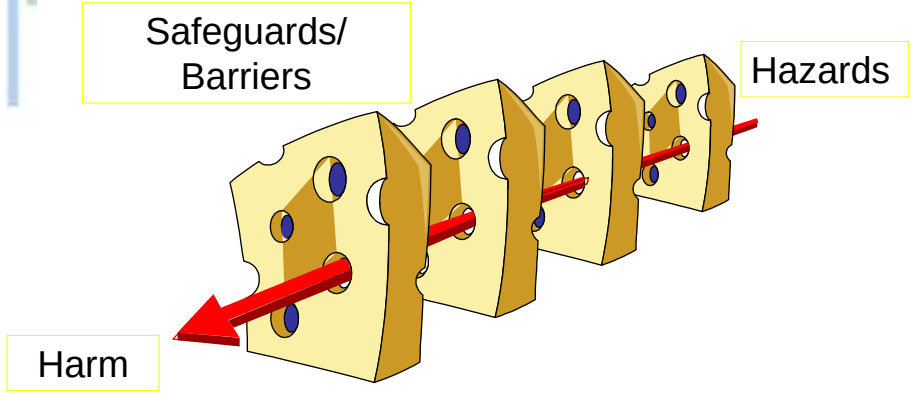
Reason's 'Swiss cheese' model (1990)



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Examples – to illustrate how data is turned into knowledge

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Death due to amiodarone

Death due to phenytoin

NHS guilty of giving baby fatal overdose

Lucas given six times too much 'heart slowing' drug

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Loading Dose Incidents

Issue

A loading dose is an initial large dose of a medicine used to ensure a quick therapeutic response. It is usually given for a short period before therapy continues with a lower maintenance dose. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

Evidence of harm

Between 1 January 2005 and 30 April 2010 there were 1,165 patient safety incidents related to loading doses reported to the National Reporting and Learning System. Of these incidents, two were fatal, four caused severe harm and 102 caused moderate harm. A further fatality was reported by coroner's letter. The fatal and severe harm incidents all related to incorrect loading doses, omitted or delayed administration of loading doses, or unintentional continuation of loading doses.

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Literature review

The need for both loading and maintenance doses creates complexity in prescribing, dispensing and administering medication, and this complexity can increase the likelihood of human error. Errors can lead to over-medication (where levels of the medication can build to excessive levels with toxic effects) or to under-medication (where harm can result from failure to effectively treat the patient's illness).

A broad literature search* in Athens using the key words 'loading dose' and 'error' revealed no scholarly articles on the topic and only one case study from America[1]. It therefore appears that errors involving loading doses and subsequent maintenance doses are an under-recognised risk.

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The value of incident reports with low harm or no harm outcomes?

- Death
- Severe harm
- Moderate harm
- Low harm
- No harm

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Table 1: Incidents by corrected severity and review of error type

Error type following review	Degree of harm (checked and corrected by clinical review)					TOTAL	
	Death	Severe	Moderate	Low Harm	No Harm	Total (N)	Total (%)
Incorrect loading dose prescribed or administered	1	1	46	112	313	473	41
Omitted and delayed administration of loading dose		2	30	71	182	285	24
Communication and documentation of loading dose and/or subsequent maintenance			8	17	78	101	9
Maintenance dose prescribed/administered at an incorrect time			5	15	72	92	8
Loading dose repeated in error			6	23	51	80	7
Loading dose continued for maintenance without dose change	1	1	5	6	39	52	4
Maintenance dose not prescribed/administered after loading dose			1	6	21	28	2
Loading dose given but not required			2	6	20	28	2
Administration rate of maintenance dose delivered as per loading dose			1	7	18	26	2
TOTAL	2	4	102	263	794	1165	

Table 2: Medication involved in reported incidents

Name of medication in incident	Degree of harm (checked and corrected by clinical review)					Total
	Death	Severe	Moderate	Low Harm	No Harm	
warfarin		**2**	**13**	**33**	**97**	**145**
amiodarone			**11**	**26**	**75**	**112**
digoxin			**15**	**25**	**59**	**99**
phenytoin	**2**		**13**	**14**	**34**	**63**
metronidazole			1	7	54	62
caffeine			6	13	41	60
aminophylline			6	18	35	59
heparin			4	17	27	48
teicoplanin			1	10	32	43
vancomycin		1	2	12	26	41
trastuzumab				3	36	39
paracetamol				5	28	33
clopidogrel			3	5	20	28
morphine			2	5	18	25
gentamicin			2	3	15	20
tirofiban			2	5	12	19
magnesium sulphate				2	11	13
benzylpenicillin				1	8	9
aspirin				2	6	8
quinine			1	2	3	6
cefotaxime			1	2	3	6
caspofungin			1	3	2	6
phenobarbitone			1	2	3	6
omeprazole				1	5	6
Other medications or unknown (62)						209
Total						**1165**

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For IMMEDIATE ACTION by all organisations in the NHS and independent sector. Deadline for ACTION COMPLETE is 25 November 2011.

An executive director, nominated by the chief executive, working with the lead pharmacist and relevant medical/nursing staff should ensure:

1. All medicines used by the organisation that are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed and administered correctly are risk assessed and used to produce a list of critical medicines (which may contain speciality subsections). This must include warfarin, amiodarone, digoxin, phenytoin and any other medicines identified locally.

2. There is effective communication regarding loading dose and subsequent maintenance dose regimens when prescribing, dispensing or administering critical medicines. This should include handover of patients between healthcare organisations. Tools such as loading dose work sheets, loading dose prescription charts, handover and clinical protocols, and patient-held information should be considered.

3. Clinical checks are performed by medical, nursing and pharmacy staff (when available) so that loading and maintenance doses are correct. Appropriate information should be available to support these checks.

4. Healthcare professionals in the community know when to challenge abnormal doses of the identified critical medicines.

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Other actions

In hospitals
Risk assess the storage of loading dose injectables as ward stock

In primary care
Challenge high dose therapy:

Digoxin > 250microgram daily in adults and > 125microgram > 70 years of age

Amiodarone doses higher than 200mg daily should be queried (the maximum licensed dose for maintenance is 200mg).

Phenytoin doses greater than 500mg daily

Warfarin doses >5mg daily

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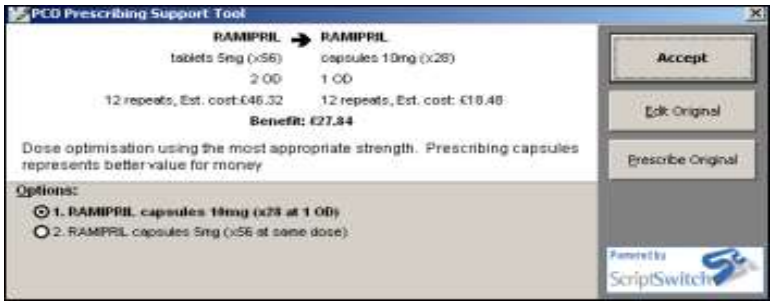
Alert screens for GP prescribing systems



Proposed loading dose message
Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death. Confirm the loading dose, frequency and duration of treatment. Consider whether the patient should be on a maintenance dose instead.

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Reducing harm from omitted and delayed medicines in hospital

- Between September 2006 and June 2009, the NPSA received reports of
- 27 deaths
- 68 severe harms
- and 21,383 other patient safety incidents
- Of the 95 most serious incidents, 31 involved anti-infectives (antibiotic and antifungals), and 23 involved anticoagulants.

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Examples of incidents

- '*Diagnosed with pulmonary embolus. Stat dose of enoxaparin (Clexane) prescribed but does not appear to have been given. Patient arrested and died.'*

- *The potassium level was 6.9. Prescribed salbutamol nebuliser, calcium resonium and actrapid insulin with Dextrose. On Attended the next morning, patient arrested at 19.40hrs and from drug kardex prescribed medication was not given. Nursing staff were informed of prescription at 17.00hrs after doctor wrote it and were told it needed giving straight away.'*

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Omitted medicine incidents causing death or serious harm

Therapeutic Group	Clinical outcome		Total
	Death	Severe harm	
Anti-infectives (Antibiotics and antifungals)	9	22	31
Anticoagulants	6	17	23
Resuscitation medicines	5		5
Insulin	2	1	3
Cardiovascular	1	3	4
Antiplatelets	1		1
Antiretrovirals		8	8
Anticonvulsants		3	3
Clotting agent		2	2
Proton Pump Inhibitor		2	2
Bronchodilators		1	1
Chemotherapy		1	1
Multiple		1	1
Oxygen		1	1
Steroid		1	1
Antagonist for respiratory depression	1		1
Immunoglobulin	1		1
Anticholinesterase		1	1

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Causes of omitted and delayed medicines

- intention to prescribe – not prescribed
  - new medicines or doses for a set course of medicine
  - routine regular medicine;
- medicine – not available – normal working hours;
- medicine – not available – out of hours;
- medicine – not administered;
- patient not on ward;
- unfamiliar preparation, administration, method or device;
- route of administration not available;
- medicine administered to wrong patient;
- discharge medicine not supplied.

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NPSA guidance on omitted and delayed medicines

1. Highlight risk of death and harm from this cause to staff
2. Identify a list of critical medicines where timeliness of administration is crucial
   - This list should include anti-infectives, anticoagulants, insulin, resuscitation medicines and medicines for Parkinson's disease, and other medicines identified locally
3. Medicine procedures
4. Regular audit of omitted and delayed critical medicines and where necessary improvements to reduce harm from omitted and delayed medicines are made

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The timeliness of medicine administration

Most medicines should be administered plus or minus two hours from the time prescribed on the inpatient prescription.

The are some specific medicines and situations where administration should be much closer to the prescribed time or clinical indication.

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Alert

Patient Safety Alert

NPSA/2011/PSA003
30 March 2011

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The adult patient's passport to safer use of insulin

Insulin is frequently included in the list of top 10 high alert medicines worldwide. Insulin treatment has been identified as an important cause of hospital admissions, mainly as a consequence of severe hypoglycaemia. The costs of managing hypoglycaemia in the UK are significant.

For action by all organisations in the NHS and independent sector where insulin is initiated, prescribed, dispensed, administered or monitored.

An executive director, nominated by the chief executive, working with

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Analysis Nov 2003 – Nov 2009

Degree of harm†	Incidents	Percentage
Death	6	<<1%
Severe	12	<<1%
Moderate	1042	6%
Low Harm	2914	18%
No Harm	12,626	76%
Total	16,600	100%

Incidents were reported at all stages of the medication process. The majority (61 per cent) occurred during insulin administration with a further 17 per cent caused by prescribing errors and 10 per cent at dispensing.

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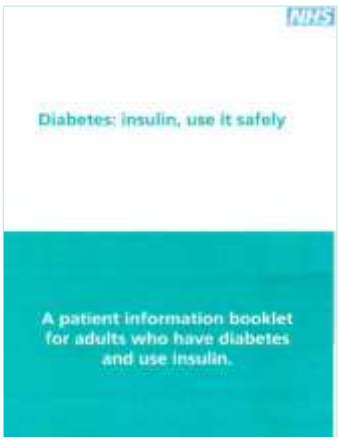
Analysis Nov 2003 – Nov 2009

Medication Error Type	Incidents	Percentage*
Wrong dose, strength or frequency	4,256	26%
Omitted or delayed doses	3,390	20%
Wrong insulin product	2,390	14%
Other	6,564	40%
Total	16,600	100%



About this booklet

This booklet explains how you could help yourself be safer when using your insulin. It explains about an Insulin Passport and helps you understand about errors or mistakes that are very unlikely but could happen to you. Advice is given to help you avoid these problems.

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A patient was given NovoRapid by mistake instead of NovoMix 30. This gave them a 'hypo' and they became confused and fell. Luckily the patient was found by his son and taken to hospital.

For example, we know these insulin names have been mixed up.

glulisine with glargine	different Hypurin products
Humalog, Humalog Mix25	
or Humalog Mix50	Lantus with lente
Humulin S, Humulin I or Humulin M3	Levemir with Lantus
Humalog with Humulin	NovoRapid with NovoMix 30

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The Insulin Passport

As a person with diabetes using insulin, you can choose to carry a credit-card sized paper record called the Insulin Passport. It can be used to record:

- up-to-date details of the type of insulin, syringes and pens that you use;
- emergency information that tells people what to do if you are found ill or unconscious; and,
- other information to help in an emergency, including contact names and telephone numbers and other medication that you could be taking.

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Insulin Passport

Please unfold for important information on insulin use


Insulin Passport

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Instructions

You should complete as much information for your passport as possible, then fold it back to credit-card size.

Keep it with you for emergencies and for reference when insulin products are prescribed or dispensed.

The area below is not for use as a daily diary record.

In the table below you should record information of your current insulin products. Provide as much detail as th
all your insulin products are clearly identified. A healthcare professional can help you with this. If someon
else has added information, ask them to sign it. You must keep this information up-to-date. Keep the passport wi
you and when you need to contact a healthcare professional, show it to them. They can use the information
help identify exactly what insulin products you use.

Date started	Date stopped	Insulin: Brand name	Presentation (for example, vial, cartridge or prefilled pen) and device for insulin administration	Signature

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Self administration of insulin in hospitals

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An infrastructure for patient safety and medication safety

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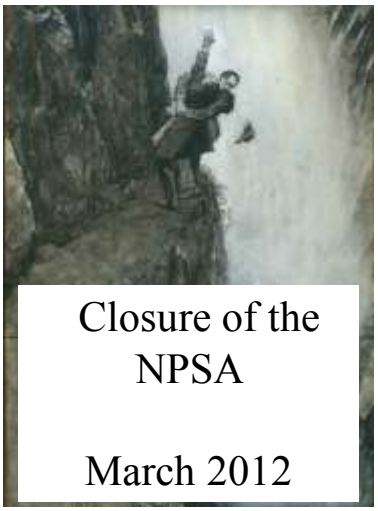

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