

Public-health burden of medication errors and how this might be addressed through the EU pharmacovigilance system

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Boy, 5, dies after being given SEVEN times too much of epilepsy drug

A boy of five died after being given a massive drug overdose in a hospital.

Bailey Ratcliffe, who suffered from epilepsy, was admitted after having several seizures.

He was given seven times too much of an anti-epilepsy drug by mistake.



Baby dies after blundering doctors gave him **TWELVE** times the normal dose of epilepsy drugs

A seven-month-old baby boy died after doctors gave him 12 times the correct amount of anti-epileptic drugs he should have received in 24 hours, an inquest heard.

Lucas Holzscheiter died at Homerton Hospital in Hackney, east London, as a result of the massive accidental overdose.

Medical staff involved in his care, including a consultant paediatrician, a specialist registrar and a senior house officer, were suspended from prescribing medicine and could still face disciplinary action.



Mother-of-four dies after blundering nurse administers TEN times drug overdose

A mother-of-four died after a nurse at a trouble-hit hospital trust gave her ten times the amount of drugs she was supposed to receive.

Arsula Samson, 80, had a heart attack at Good Hope Hospital, Birmingham, after she was given an overdose of deadly potassium chloride.



Two cancer patients 'died just hours after being given medication overdose'

Two cancer patients died hours after being given overdoses of drugs used to combat side-effects of their treatment.

Paul Richards, 35, and Baljit Singh Sunner, 36, were given up to five times the recommended dose.

They died within hours of each other at Heartlands Hospital in Birmingham, where both were being treated for different forms of cancer.

A jury of seven has heard confusion was caused over Amphotericin having various forms and doses.

The original "conventional" Amphotericin, branded as Fungizone, is prescribed at around one milligram per kg of a patient's weight, while modern forms are branded as Ambizone and Ambleset, with dosages of three milligrams per kg and five milligrams per kg.



Diabetic patient unlawfully killed after newly qualified nurse gave her TEN times too much insulin

A diabetic pensioner who was injected with ten times too much insulin was unlawfully killed, a coroner has ruled.

The inquest heard community nurse Joanne Evans gave the lethal overdose after putting a decimal point in the wrong place - injecting Margaret Thomas, 85, with 3.6ml of insulin instead of 0.36ml.

She died about six hours after Ms Evans administered the overdose.



Widow, 71, died after doctors ignored penicillin warning

A grandmother died after hospital doctors gave her penicillin even though her medical notes and drug chart made clear she was allergic to it.

June Cutmore was even wearing a red wristband to draw attention to the allergy.

The 71-year-old widow went into anaphylactic shock and died after being injected with Augmentin - a form of the drug.



Teenager dies after drug error



Donna Horn: Doctor was blamed for her death

AT THE age of 23, Donna Horn from Wellingborough, Northamptonshire, achieved her ambition to visit Disney World in Florida.

Making the trip in 1998 was a triumph for Donna, but it was not without its difficulties. Her wheelchair made the journey far from easy and she was suffering from a chest infection.

But while she was away, the illness deteriorated and she died. Doctors said her paralysis had probably aggravated the chest infection which finally killed her.

What also came out at this week's inquest into Donna's death, however, was that the paralysis itself was the result of a medical blunder.

At the age of 15, Donna, like Wayne Jowett, the 18-year-old who died yesterday in Nottingham, had been fighting the blood cancer leukaemia. She had been diagnosed three years earlier and, like Wayne, she seemed to be beating the disease. Like him, however, she was



Wayne Jowett, who died after doctors injected an anti-cancer drug into his spine

said: "It was a genuine mistake from a lapse of concentration."

After completing his evidence, Dr Grealley turned to Donna's family and apologised. Later Donna's sister Amanda

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campaigners who want the rules tightened up so that the same mistake is not made again. And they are already realising with growing horror that Wayne is not the first to die in this wholly preventable way.

Paul Balen, the family's solicitor, said: "My clients have been appalled to learn that so many other families have suffered as a result of similar mistakes."

He said that Wayne had been in remission at the time of the blunder, indicating that the blood cancer appeared to be under control.

Two junior doctors at the hospital have been suspended and the police have been called in to investigate Wayne's death.

John MacDonald, the chief executive of the Queen's Medical Centre, admitted his staff and the hospital had let the Jowett family down.

Mr MacDonald said: "We have failed Wayne and his family and for that we are deeply sorry. We apologise unreservedly to the family and would like to express our deepest sympathy."

He added: "A serious mistake was made when Wayne's drug treatment was administered wrongly."

Mr MacDonald said staff had been reminded to follow strict protocols and procedures for administering such drugs to patients. He said: "A full internal

inquiry has already been started to discover what went wrong. And if there are any lessons to be learnt from this then they will be."

Nottinghamshire police said they had been called in to investigate the circumstances surrounding the death.

A Department of Health spokesman said: "We are very sorry to hear of the tragic case of this young man. This is a rare and catastrophic event which has happened in this and other countries over the last 20 years."

"It is potentially avoidable and a major new initiative is being taken to try to address a problem which has not been solved by previous action."

The new initiative includes introducing a mandatory system for reporting mistakes.

Specific work on wrongly-administered spinal injections is being led by Professor Kent Woods, director of the NHS Technology Assessment Programme.

Mr Jowett's death today came just a day after the inquest on a 23-year-old Northamptonshire woman who died after a doctor in Leicester made a similar mistake. Donna Horn, who had also been receiving treatment for leukaemia, was injected in the spine with Vincristine by Dr Peter Grealley.

He admitted yesterday: "It was a genuine mistake from a lapse in concentration." jtrueland@scotsman.com

How a lifesaver becomes a killer

Jennifer Trueland

the error, then it will kill, and

be a number of reasons why

A committee chaired by the

Year	Patient details	Country
2008	Male – 37 years	India
2007	Female – 21 years old	Hong-Kong
2005	Male – 21 years old	USA
2005	Female - 58 year old	Spain
2004	Male – 28 years old	Australia
2003	Child – 2 year old	USA
2003	Male – 49 year old	USA
2002	Female – 12 year old	Spain
2001	Female – 5 year old	Germany
2001	Male – 57 year old	Germany
2001	Male – 18 year old	England
1999	Male – 12 year old	England
1999	Male – adult	England
1999	Female – 7 year old	Sauda Arabia
1999	Male – 3 year old	South Korea
1998	Female – 7 year old	Canada
1995	Child	USA

Year	Patient details	Country
1992	Child	Saudi Arabia
1991	Male – 23 year old	USA
1990	Female – 56 year old	England
1990	Female – 16 year old	England
1990	Male – 16 year old	England
1989	Adult	USA
1989	Male	Israel
1988	Female – 9 year old	England
1988	Male – 56 year old	England
1987	Female – 17 year old	Australia
1987	Female – 10 year old	England
1984	Female – 2 year old	Ireland
1983	Male – 16 year old	USA
1983	Female – 23 month old	USA
1982	Female – 8/9 year old	Israel
1980	Female – 29 year old	USA
1978	Female – 5 ½ year old	USA
1968	Female - 2 ½ years	USA

Patient Safety - Definition

- Patient Safety is the freedom from accidental injury in healthcare.
- Adverse events may result from problems in practice, products, procedures or systems.
- Patient safety improvements demand a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care.

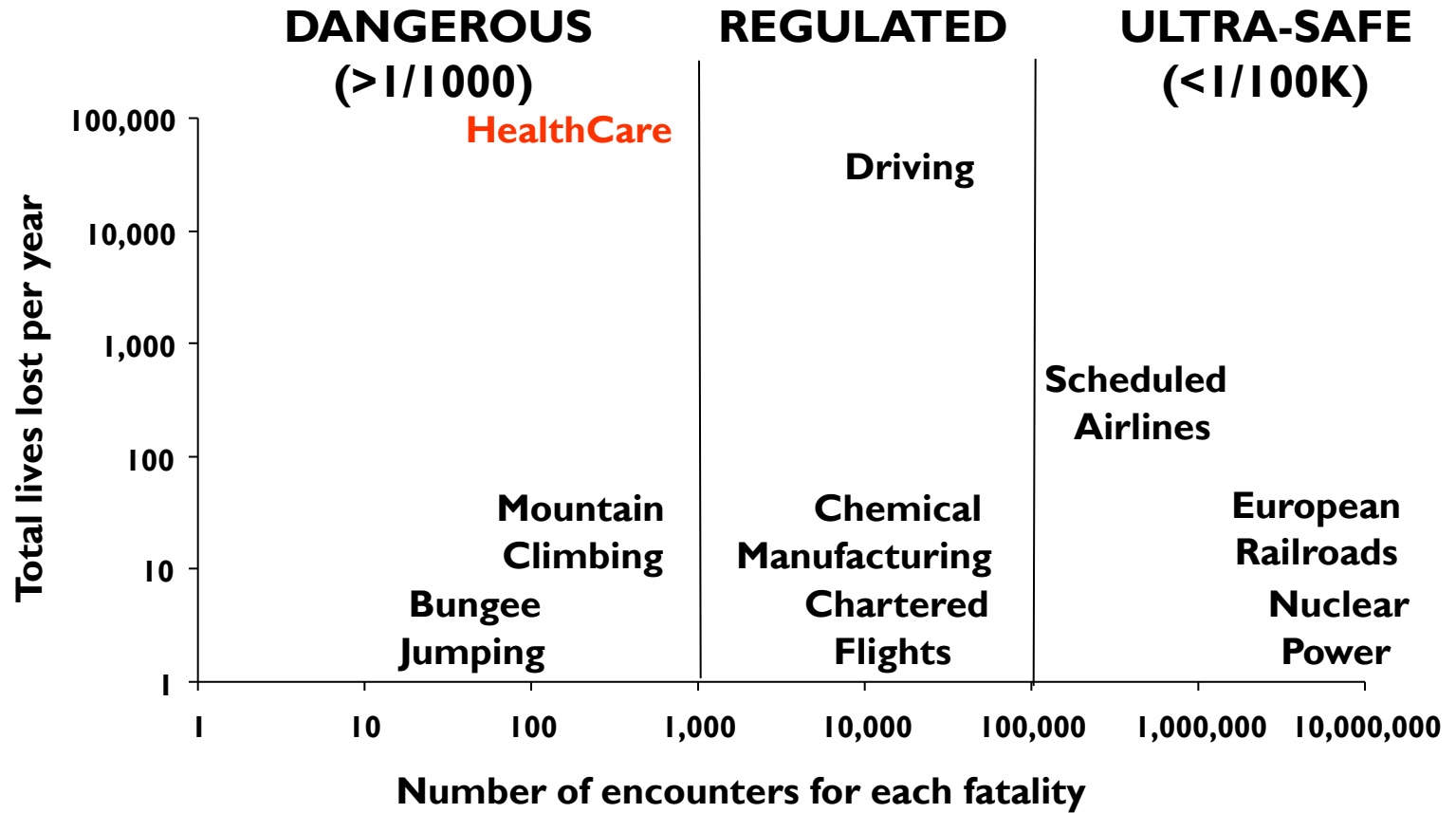
Adverse events in healthcare systems

	Study	Study focus (date of admissions)	Number of hospital admissions	Number of adverse events	Adverse event rate (%)
1	United States (Harvard Medical Practice Study)	Acute care hospitals (1984)	30 195	1 133	3.8
2	United States (Utah–Colorado study)	Acute care hospitals (1992)	14 565	475	3.2
3	United States (Utah–Colorado study) ^a	Acute care hospitals (1992)	14 565	787	5.4
4	Australia (Quality in Australian Health Care Study)	Acute care hospitals (1992)	14 179	2 353	16.6
5	Australia (Quality in Australian Health Care Study) ^b	Acute care hospitals (1992)	14 179	1 499	10.6
6	United Kingdom	Acute care hospitals (1999–2000)	1 014	119	11.7
7	Denmark	Acute care hospitals (1998)	1 097	176	9.0

Source: World Health Organization, Executive Board 109th session, provisional agenda item 3.4, 5 December 2001, EB 109/9.

a Revised using the same methodology as the Quality in Australian Health Care Study (harmonising the four methodological discrepancies between the two studies).

b Revised using the same methodology as Utah–Colorado Study (harmonising the four methodological discrepancies between the two studies). Studies 3 and 5 present the most directly comparable data for the Utah–Colorado and Quality in Australian Health Care studies.



Preventable deaths in English acute hospitals

- Retrospective case record reviews of 1000 adults who died in 2009 in 10 acute hospitals
- Reviewers judged 5.2% of deaths as having a > 50% of being preventable (11,859) patients
- Poor clinical monitoring 31%,
- Diagnostic error 30%,
- Drug or fluid management 21.1% (2,502)

Quality of care: patient safety

Concerned that the incidence of adverse events is a challenge to quality of care, a significant avoidable cause of human suffering, and a high toll in financial loss and opportunity cost to health services;

Noting that significant enhancement of health systems' performance can be achieved in Member States by preventing adverse events in particular, and improving patient safety and health care quality in general;

Recognizing the need to promote patient safety as a fundamental principle of all health systems,

1. URGES Member States:

(1) to pay the closest possible attention to the problem of patient safety;

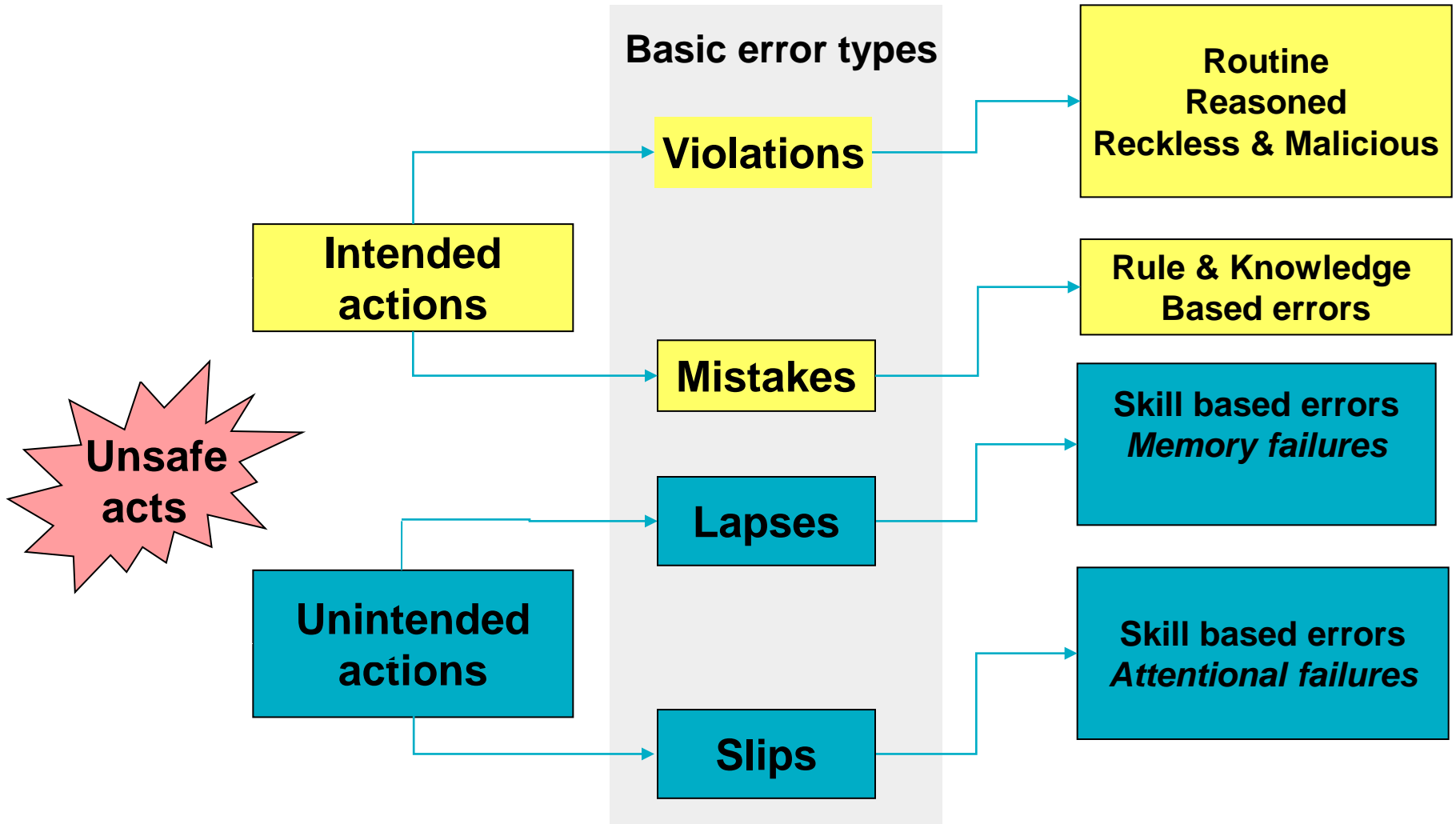
(2) to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology.

Learning from other safety critical industries

To minimise patient safety incidents, healthcare should learn from other safety-critical industries and target the underlying systems failures.



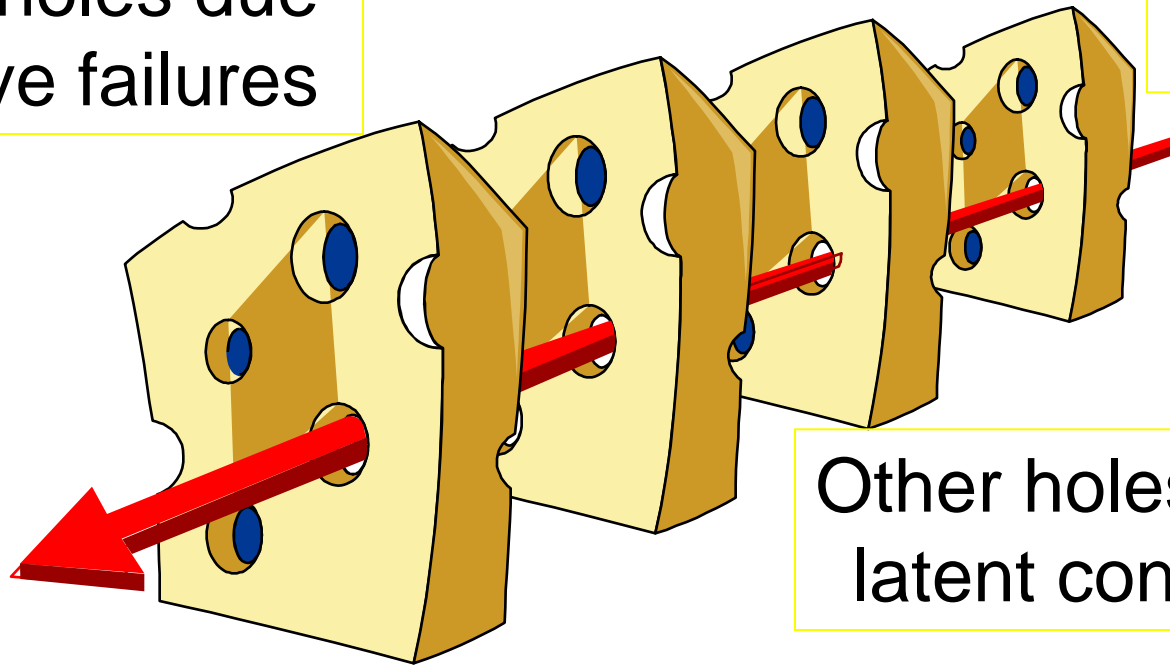
Human factors



Reason's 'Swiss cheese' model (1990)

Some holes due to active failures

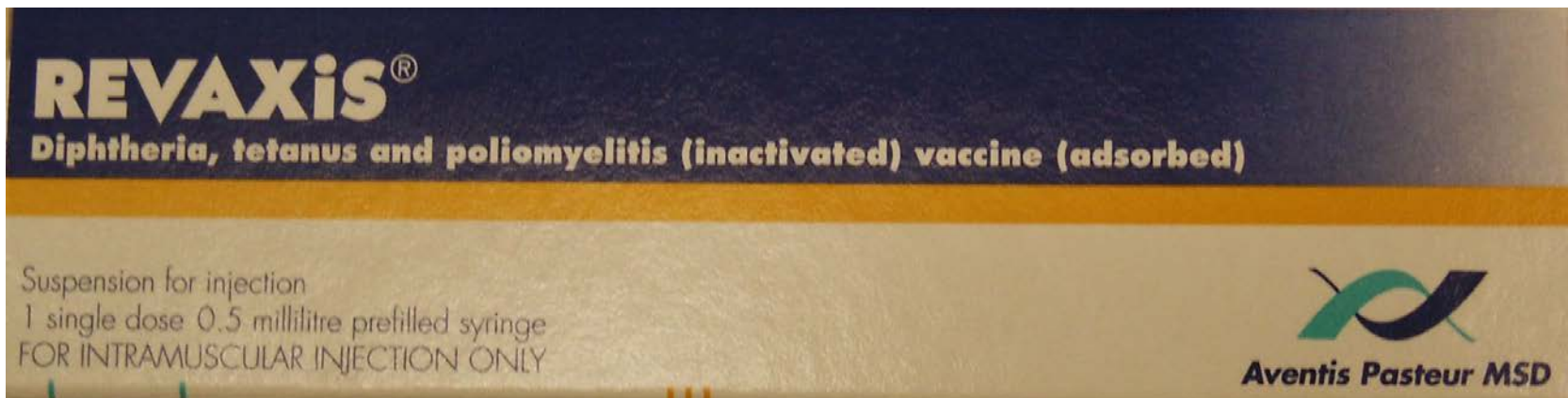
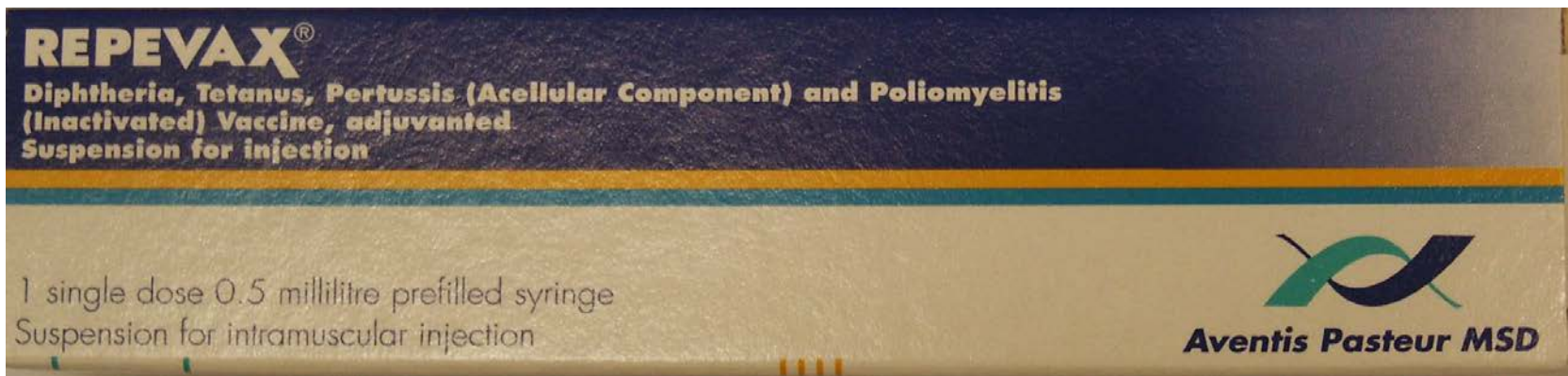
Hazards



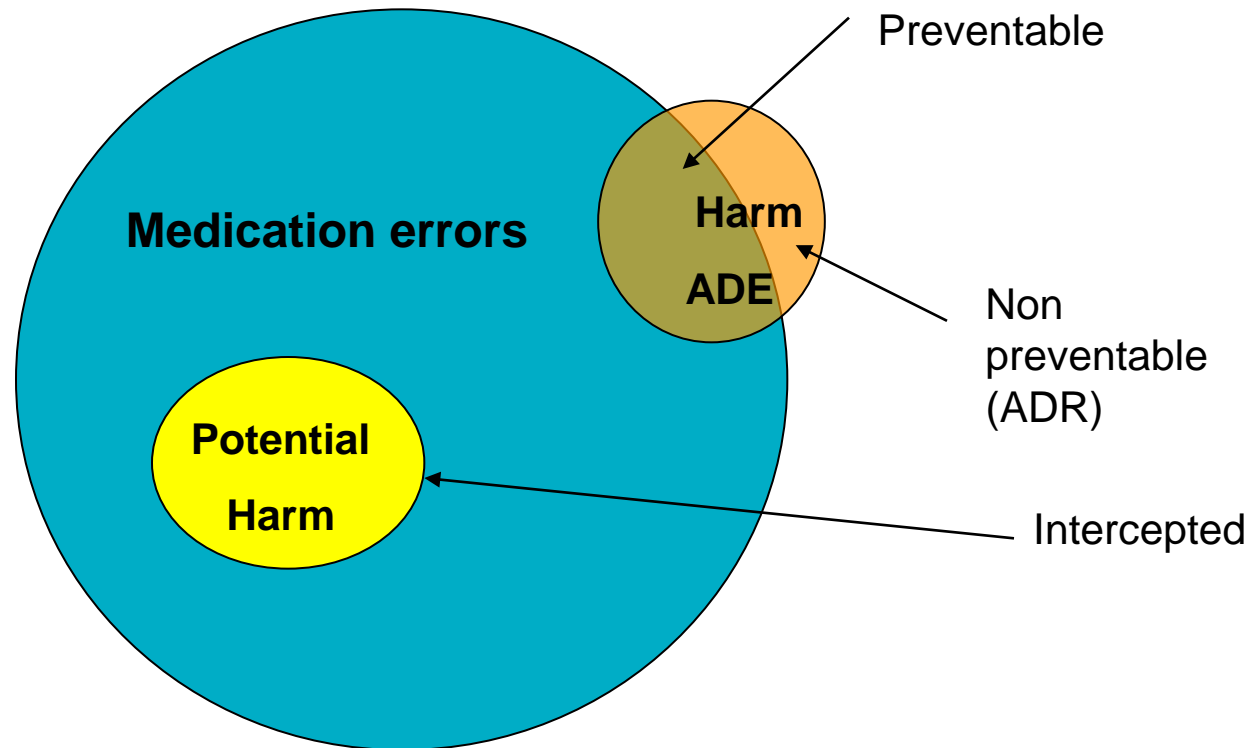
Losses

Other holes due to latent conditions

Error prone naming, labelling and packaging



ADE's ADR's and Medication Errors (Bates 1995)



Preventable harms from medicines in community practice in the UK

1. Prescribing errors

- 1 in 20 items with an error – 1 in 550 with a serious error
- 1 billion items in 2012 = 1.8 Million serious prescribing errors

2. Dispensing errors

- 1.7% dispensing error and 1.6% labelling errors
- 33% 'serious errors' – 10.9 million in 2012

3. Preventable medicines related admissions to hospital

- 4.68% of emergency admissions – 250,000 admissions

- Avery et al. The PRACtICe Study. (Prevalence And Causes of prescribing errors in general practice). A report for the GMC.2012; at www.GMC-UK.org
- Dean Franklin and O'Grady Int J Pharm Pract 2007;.15: 273-281
- Pirmohamed et al Brit Med J. 2004; 329:15-9

Types of pADE's in ambulatory care

- For pADEs requiring hospital admission, the most frequent drug therapy problem and error of omission reported was inadequate monitoring (45.4%; range 22.2-69.8%)
- Failure to prescribe prophylaxis to patients taking nonsteroidal anti-inflammatory drugs or antiplatelet drugs frequently caused gastrointestinal toxicity, whereas lack of monitoring of diuretic, hypoglycemic, and anticoagulant use caused over- or under-diuresis, hyper- or hypoglycemia, and bleeding

Errors rates in hospital

Prescribing errors

- Research studies between 1985 to October 2007. Prescribing errors in adult or child hospital giving enough data to calculate an error rate.
- Prescribing errors are a common occurrence, affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions.

Lewis P J and Dornan T. et al Drug Saf. 2009;32:379-89

Dispensing errors

- Error rate in hospital pharmacy 0.02 – 2.7%.

James K and Barlow D et al Int J Pharm Pract 2009;17:9-30

Administration

- Research publication between 1995 – 2009
- administration error rates in adult general wards 3–8%

Kelly J and Wright D . Journal of Clinical Nursing 2012; 21: 1806-15

Dispensing errors

- Research publications between 1966 to February 2008 were searched for studies indicating dispensing error rates
- Sixty papers were identified investigating dispensing errors in the UK, US, Australia, Spain and Brazil
- Error rate in community pharmacy 0.01% - 3.32%
- Error rate in hospital pharmacy 0.02 – 2.7%.

National Reporting and Learning System (NRLS) in England and Wales medication incident reports 2005 - 10

Year	Total number of incident reports*	Number of medication incident reports†	Medication incident reports as a percentage of all incident reports received
2005	517415	42398	8.19
2006	742418	64484	8.69
2007	874148	79118	9.05
2008	986981	94280	9.55
2009	1118336	113837	10.18
2010	1198701	132069	11.02
Total	5,437,999	526,186	

National Reporting and Learning System (NRLS) in England and Wales medication incident reports 2005 -10

Stage of medication process	Incidents	Percent of medication incidents
Administration of medicines	263228	50.01
Prescribing of medicines	97097	18.45
Preparation / dispensing of medicines	87057	16.54
Other	48410	9.20
Monitoring / follow-up of medicine use	23648	4.49
Advice	3537	0.67
Supply or use of over-the-counter (OTC) medicine	3045	0.58
N/A	240	0.05
(blank)	117	0.02
Other / Unspecified	48410	9.20
Total	526379	100.00

NRLS – Error category

Category of error	Incidents	Percent of medication incidents
Omitted and delayed medicine	82028	15.58
Wrong dose or strength	80170	15.23
Wrong medicine	48834	9.28
Wrong frequency	44165	8.39
Wrong quantity	28764	5.46
Mismatching between patient and medicine	21915	4.16
Wrong / transposed / omitted medicine label	13755	2.61
Patient allergic to treatment	11695	2.22
Wrong formulation	11254	2.14
Wrong / omitted / passed expiry date	10998	2.09
Wrong storage	10447	1.98
Unknown	10024	1.90
Wrong method of preparation / supply	9840	1.87
Wrong route	7934	1.51
Contra-indication to the use of the medicine in relation to medicine or condition	7632	1.45
Adverse drug reaction (when used as intended)	5939	1.13
Wrong / omitted verbal patient directions	1383	0.26
Wrong / omitted patient information leaflet	1156	0.22
Blank	129	0.02
Other/not specified	118317	22.48
Total	526379	100.00

NRLS – Critical medicines

Medicine or therapeutic group*	Death	Severe	Total	Percentage of medication incidents with fatal and severe harm outcome†
Opioids	46	43	89	10.83
Antibiotics	10	38	48	5.84
Warfarin	15	30	45	5.6
LMWH‡	23	23	46	5.6
Insulin	9	37	46	5.6
Benzodiazepines	15	12	27	3.28
NSAIDs§	1	17	18	2.19
Potassium	7	8	15	1.82
Adrenaline	8	4	12	1.46
Phenytoin	1	11	12	1.46
Amiodarone	3	4	7	0.85
Anti-psychotics	2	5	7	0.85
Methotrexate	2	3	5	0.61
Total	142	235	377	45.99



Alert

Promoting safer use of injectable medicines

Actions that can make anticoagulant therapy safer

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

Safer spinal (intrathecal), epidural and regional devices – **Part A**

Rapid Response Report

NPSA/2010/RRR009

From reporting to learning

24 February 2010

Reducing harm from omitted and delayed medicines in hospital

Preventing fatalities from medication loading doses

Risks of incorrect dosing of oral anti-cancer medicines

Safer ambulatory syringe drivers

Safer administration of insulin

Reducing Dosing Errors with Opioid Medicines

Design for patient safety

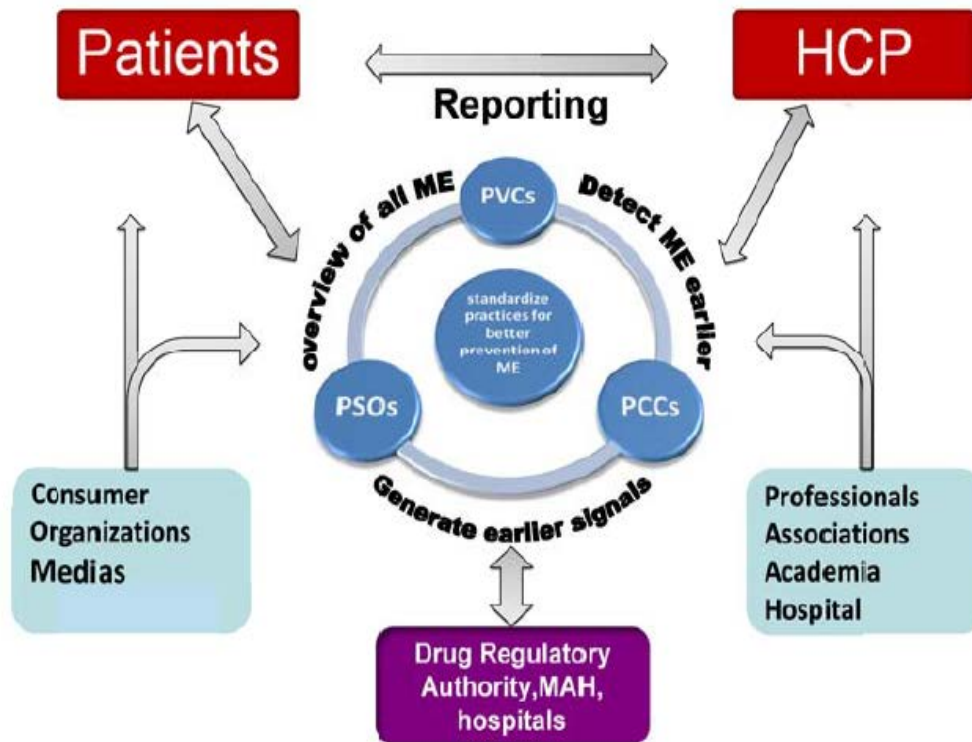
A guide to labelling and packaging of injectable medicines

Guidelines for safe on-screen display of medication information

Medication errors in ADR databases

- In Morocco, a retrospective analysis of the national pharmacovigilance database showed that 14% of all suspected adverse drug reactions were preventable.
- Medication errors associated with preventable adverse drug effects and related to the medication use system occurred most often at the stages of prescribing (36%) and administration (34%)
- Soulaymani et al .British Journal of Clinical Pharmacology. 2009; 67:6 687-690.
- EU FP7 Funded WHO Project – Managing Medicines – Uppsala Monitoring Centre
- Reporting and learning – medication errors in pharmacovigilance centres

1st, 2nd, 3rd and 4th level of Partnerships



PSO's examples:

- Institute's For Safe Medication Practices: USA, Canada, Spain, Brazil
- National Reporting and Learning Service/NHSCB
- Danish Patient Safety Society
- Dutch hospital pharmacy association
- Australian Commission on Safety and Quality in Healthcare

International Medication Safety Network.

www.intmedsafe.net

Harms from medication errors and the EU pharmacovigilance system

- Broader view of patient safety
- Not just ‘product’ focused
- Greater understanding of systems of use and human factors
- Link to use of medical devices to prescribe, prepare and administer medicines
- Broader and new categories and methods for reporting and learning
- New methods to identify, communicate, risks and solutions and implement and sustain safer practice
- Improved review of design of naming, labelling and packaging
- Better use of risk management plans
- Better use of technology – e-prescribing, dispensing – administration
- Use of bar codes – for more than anti-counterfeiting