# Improving patient safety – incident reporting and learning


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# My path to Slovenia

- Pharmacist
  - Community and industry
  - Hospital
    - Clinical, medicines information
    - Medication safety coordinator
  - Founded Irish Medication Safety Network
  - Founder member of International Medication Safety Network
  - Health Service Executive
    - Clinical Lead, National Medication Safety Programme
  - Advisor to WHO (Medication Without Harm Challenge, Patient Safety)
  - European Medicines Agency

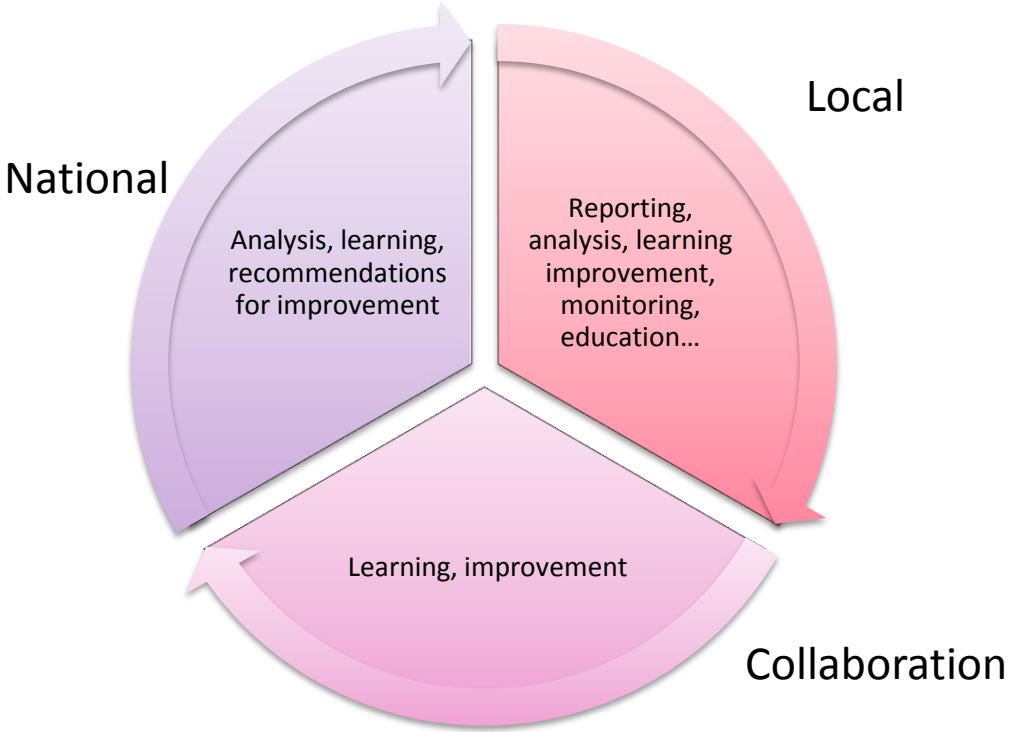
# Harm and error rates with medication

- Approx 6.5% of admissions experience an adverse drug event (ADE) i.e. harm
  - Bates et al, JAMA 1995;274:29-34
- 49% of IV doses administered with at least one error
  - Taxis and Barber, BMJ 2003;326:684-687
- 6.5% of admissions have an Adverse Drug Reaction (ADR) i.e. harm; the ADR was the cause of admission in 80% of these
  - Pirmohammed et al, BMJ 2004;329:15-19
- Similar rates of error in paediatrics, but three times more likely to suffer harm
  - Kaushal et al, JAMA 2001;285:2114-20
- One medication error per hospital in-patient per day
  - Institute of Medicine, Preventing Medication Errors, 2006

- Every system is perfectly designed to get the results it gets

  – Paul Batalden

# Reporting, learning and improvement

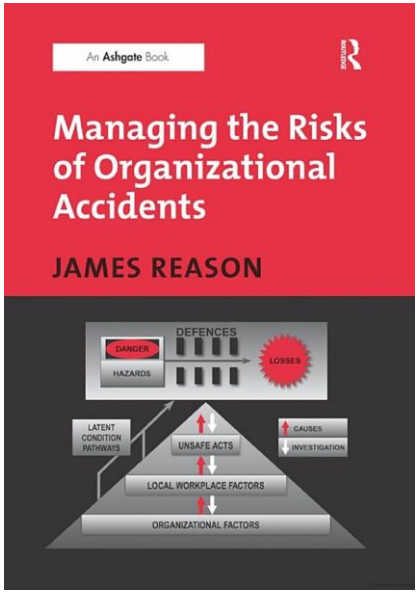


# Local – hospital learning & improvement

# Local - hospital

- Safe systems
- Accept incidents and harm happen, want to avoid in future
- Report incidents and near misses
  - Non-punitive
  - Confidential
  - Inform line manager and team too
- Open communication with the patient if harm
  - With knowledge of consultant
- Learn from errors/near misses – analysis with staff
- Act on learning – systems improvements, sharing
- Safer systems

# Key influences




- Tim Delaney, Tallaght Hospital Dublin
- Institute for Safe Medication Practices www.ismp.org
- Veteran's Administration
- www.nccmerp.org
- National Patient Safety Agency, UK
- James Reason (Managing the Risks of Organisational Accidents)
- Incident and risk management – RCA / Systems analysis, risk rating/register
- Colleagues in www.imsn.ie and www.intmedsafe.net
- Human factors
- Deming

# Healthcare Myths

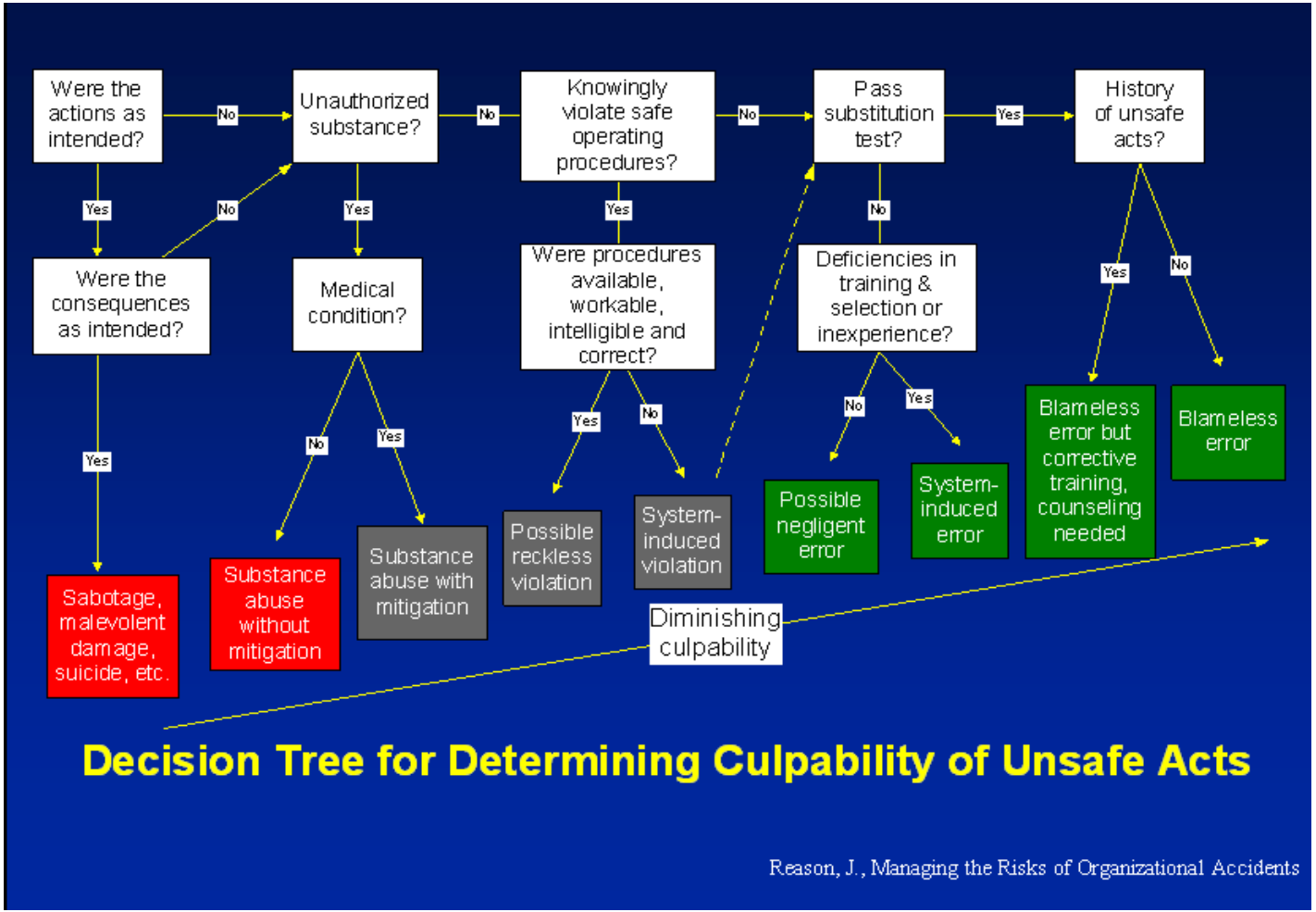
- Myth of perfection

- Myth of punishment

# Safety Culture

(Westrum, 2004)

| Pathological Culture | Bureaucratic Culture | Generative Culture |
|---|---|---|
| Don't want to know | May not find out | Actively seek it |
| Messengers (whistle-blowers) are **shot** | Messengers are listened to *if they arrive* | Messengers are *trained and rewarded* |
| Responsibility is *shirked* | Responsibility is *compartmentalised* | Responsibility is *shared* |
| Failure is punished or *concealed* | Failures lead to *local repairs* | Failures lead to *far-reaching reforms* |
| New ideas are actively discouraged | New ideas often present problems | New ideas are welcomed |


Were the actions as intended?
No
Unauthorized substance?
No
Knowingly violate safe operating procedures?
No
Pass substitution test?
Yes
History of unsafe acts?
Yes
Were the consequences as intended?
No
Yes
Medical condition?
Yes
Were procedures available, workable, intelligible and correct?
Yes
Deficiencies in training & selection or inexperience?
No
Yes
No
Yes
No
Yes
No
Yes
No
Yes
Sabotage, malevolent damage, suicide, etc.
Substance abuse without mitigation
Substance abuse with mitigation
Possible reckless violation
System-induced violation
Possible negligent error
System-induced error
Blameless error but corrective training, counseling needed
Blameless error
Diminishing culpability
Decision Tree for Determining Culpability of Unsafe Acts
Reason, J., Managing the Risks of Organizational Accidents

# Designing systems with human factors in mind

Remove the hazard

Forcing functions and constraints

Automate, IT - carefully

Standardise, simplify

Checklists, protocols

Independent double-checking

Improve information access

Decrease transcription & look-alikes

Rules and policies

Education and information

"Try harder"

Ref: Veteran's Health Administration Center for Patient Safety hierarchy for patient safety solutions

# Non-punitive, system-based incident reporting policy to promote medication safety

**Communicating with patients and families after and adverse event**

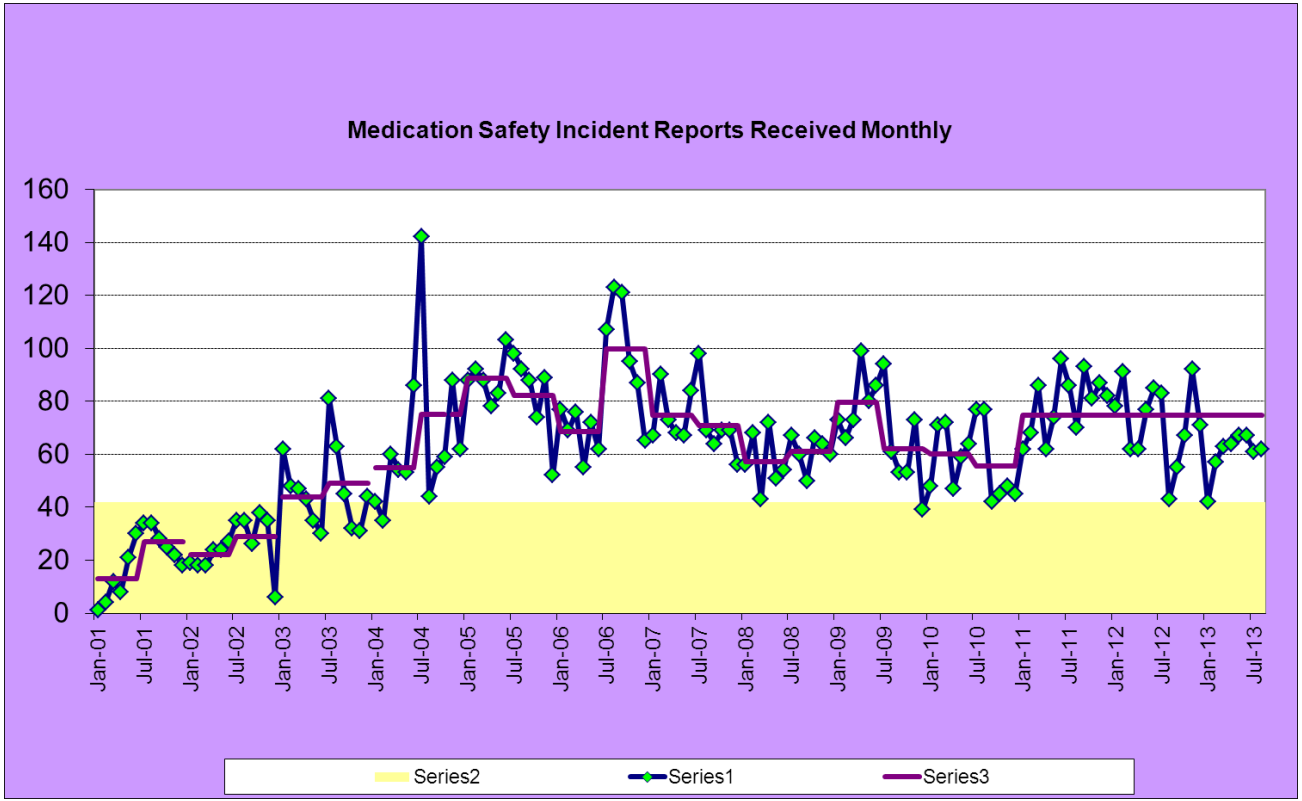
As soon as it is apparent that a health care **injury** has occurred, the patient or next of kin are entitled to a prompt explanation of how the injury occurred and its short- and long-term effects. Injury may be caused in circumstances where the standard of care and the prescribing and administration of drugs cannot be faulted, such as in the case of many untoward drug reactions. Patients should be informed that the reason for a problem needs to be investigated before it can be determined whether there was an error. When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error. They should be informed that the factors involved in the injury would be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients.

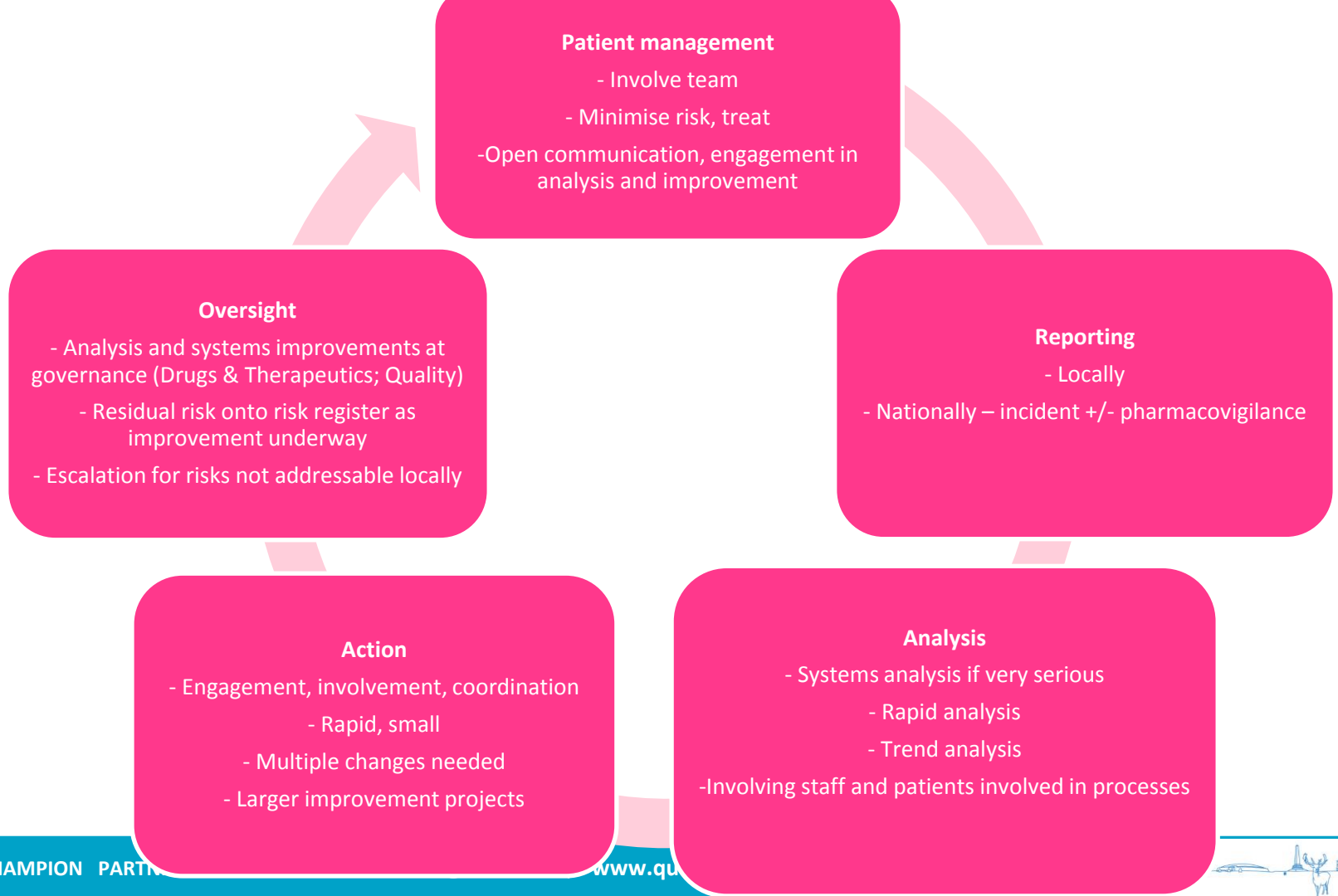
(Note: This policy statement is taken in part from the U.S. National Patient Safety Foundation *"Talking to Patients about Health Care Injury: Statement of Principle" [November 2000])*

Disclosure must be with the knowledge and approval of the consultant in charge of the patient. Where the consultant is not available and is being covered by a colleague, disclosure must be with the knowledge and approval of the covering clinician who has responsibility for the patient's care.

Patients or their carers should be told about any incident affecting them, which has been reported to a medical indemnity body.

# Incident reporting




Patient management
- Involve team
- Minimise risk, treat
-Open communication, engagement in analysis and improvement
Reporting
- Locally
- Nationally – incident +/- pharmacovigilance
Analysis
- Systems analysis if very serious
- Rapid analysis
- Trend analysis
-Involving staff and patients involved in processes
Action
- Engagement, involvement, coordination
- Rapid, small
- Multiple changes needed
- Larger improvement projects
Oversight
- Analysis and systems improvements at governance (Drugs & Therapeutics; Quality)
- Residual risk onto risk register as improvement underway
- Escalation for risks not addressable locally

# Strong defences against catastrophic error

- Methotrexate
  - Single patient-specific dose dispensed weekly only
- Vinca alkaloids
  - Prepare in minibags
- Intravenous chemotherapy – high reliability process
  - Protocols, aseptic preparation, trained staff, independent checks +++

Heparin 5 000 units SC bolus

What do you select?


# Opioid patches

- Restricted dispensing – clinical check first
- Information in Medicines Guide – equivalent doses
- Multiple alerts & information – hospital, GPs, IMSN, ISMP Canada

## Strong Opioid Transdermal Patches
**Safety Briefing**

Fentanyl (Durogesic® D Trans®, Matrifen®, Fental®) and buprenorphine (Transtec®, BuTrans®) are transdermal patches delivering a continuous dose of strong opioid to a patient over a prolonged period. **Fentanyl 25 microgram/hour patches deliver the equivalent of 90mg oral morphine/day; the BuTrans® 35 microgram/hour patch delivers the equivalent of 30-60mg oral morphine/day.**

**Healthcare professionals, patients and their carers need to understand these potent therapies, how to use and dispose of patches safely, how to recognise toxicity and what to do should it occur.**

Significant problems with fentanyl and buprenorphine patches have been reported via medication safety reporting systems in Irish hospitals[1], with many of these incidents originating in the community. Fatal events have also been highlighted internationally[2,3].

Example 1 (Ireland[1])
Older female patient experienced pain not responding to paracetamol. GP prescribed fentanyl 50 microgram/hour patch (equivalent to 180mg morphine daily). 14 day hospital admission for toxicity.

Example 2 (United States[2])
A woman placed a fentanyl patch prescribed for her on her six-year old foster child's neck, thinking it would act locally. The child was unconscious the following morning and died soon after. The woman is being charged with criminal gross negligence.

Example 3 (Canada[3])
Patient with COPD and severe back and leg pain was commenced on a fentanyl 75 microgram/hour patch (equivalent to approximately 270mg oral morphine daily). The pain persisted and dose increased three days later to 125 microgram/hour patch (equivalent to approximately 450mg oral morphine daily). Pain improved following day, patient confused that evening, patient unresponsive next morning and died.

**Initiation**
- These patches should only be used to treat **stable and chronic intractable pain**.
- Prescribers need to ensure they fully understand these potent, complex therapies and meet prescribing restrictions for fentanyl patches.
- Fentanyl patches should only be used in patients who have demonstrated tolerance to strong opioids, with the initial dose based on the previous 24 hour opioid analgesic requirement.

**Strength**
- Fentanyl and buprenorphine (Transtec®) patches deliver **high doses of a potent strong opioid**.

| Durogesic® D Trans® patch | Approximate oral morphine equivalent dose | BuTrans® patch | Approximate oral morphine equivalent dose |
|---|---|---|---|
| 25 microgram/hr | 90 mg/day | 35 microgram/hr | 30-60 mg/day |
| 50 microgram/hr | 180 mg/day | 52.5 microgram/hr | 90 mg/day |
| 75 microgram/hr | 270 mg/day | 70 microgram/hr | 120 mg/day |

- Buprenorphine (BuTrans®) patches contain a potent strong opioid, but the dose is much lower. BuTrans® 5 microgram/hour patch is approximately equivalent to morphine 7-10 mg per day.

**Onset**
- All transdermal patches have a **slow onset of action** (12 to 24 hours).
- **Phase out previous analgesic therapy gradually during the first 24 hours**.
- Titrate doses in small increments, at least 72 hours after applying the previous patch.

**Duration of action, reversal**
- Drug continues to be released from a reservoir within the skin after removal of these patches. Do not commence alternative opioid analgesia for 24 hours after removal.

- Apply new patch to dry, intact, non-hairy skin on torso or upper arm, having removed the previous patch. Do not apply a patch to the same area for at least a week.
- **Patients suffering severe toxicity should be monitored and treated if necessary for at least 24 hours after patch removal.**
- Patients scheduled for surgery should be reviewed by an anaesthetist at least 24 hours (preferably 3 days) pre-operatively to instruct when to remove the patch.

**Cautions**
- **Do not expose to heat, sunlight or radiation. Monitor for toxicity if the patient has fever.**
- The elderly, cachectic, debilitated and those with renal or hepatic impairment are particularly prone to adverse effects. They may require lower doses and slower titration.

**Adverse effects**
- **The principal signs of opioid toxicity are respiratory depression, hypotension and pinpoint pupils.** Other signs of toxicity are tiredness, extreme sleepiness or sedation, inability to think, talk or walk normally, feeling faint, dizzy or confused.
- **If toxicity is suspected, remove the patch, institute supportive measures (e.g. securing airway), consider reversal with naloxone and monitor for at least 24 hours after patch removal.** Dialysis does not remove fentanyl or buprenorphine. Naloxone is poorly effective in reversing buprenorphine toxicity and high doses may be needed.

**Adjunctive therapy**
- Prophylactic laxatives are required throughout treatment.
- A rapid onset oral opioid preparation should be prescribed for breakthrough pain e.g. Sevredol®.

**Patch care and disposal**
- Used patches may contain significant residues of active substance. After removal, fold firmly in half, adhesive side inwards, and discard safely according to the instructions in the pack.
- Do not divide, cut or damage patches, as this can lead to uncontrolled release of drug.

The information in this briefing highlights key safety issues with these products. For full information, consult the Summaries of Product Characteristics for each product[4-8] (www.medicines.ie or www.imb.ie).

**Safe prescribing and dispensing key points**
- Prescriber has appropriate knowledge and experience.
- Patient understands and is capable of following complex instructions for safe treatment.
- Patient has stable, chronic pain and, in the case of fentanyl, has been receiving strong opioids.
- Initial dose or dose increase is appropriate.
- Laxatives and analgesia for breakthrough pain are prescribed.
- Correct patch dispensed.

**Patient counselling key points key points**
- Strong opioid drug.
- Read Patient Information Leaflet fully and retain for reference.
- Slow onset of action initially.
- How, when and where on the body to apply and reapply patches.
- Precautions regarding exposure to heat.
- Signs of toxicity and what to do should they occur.
- Likelihood of constipation and need to use laxatives regularly throughout treatment.
- Safe storage and disposal.

**References**

1. Kirke C. Strong Opioid Transdermal Patches. Irish Pharmacy Journal Oct-Nov 2008, p204-206
2. Institute for Safe Medication Practices, http://www.ismp.org/Newsletters/ambulatory/archives/200806_1.asp
3. Institute for Safe Medication Practices, Canada, http://www.ismp-canada.org/download/ISMPCSB2007-05Fentanyl.pdf
4-8. Summaries of Product Characteristics, Durogesic® D-Trans®, Matrifen®, Fental®, Transtec®, BuTrans®

# Insulin pens

- Alerts, memos, engagement
- Patient-specific dispensing
- Label – warning, name
- Storage
- Needles available everywhere
- Education
- Monitoring
- Escalated nationally – collaboration – alerts
- Restricted all injectables to single-use or (insulins) one patient

## Inject Me Don't Infect Me

Drug Safety Coordinator/Infection Control/Nurse Practice Development February 2013

Use **Aseptic Non-Touch Technique** to prepare and administer injectable medication and fluids[1].

### Single Use

All single-dose drug ampoules/vials (most drug products, e.g. antibiotics), infusion fluids, syringes, needles, cannulae, administration sets and connectors are for:


**One patient, one time, then discard immediately.**

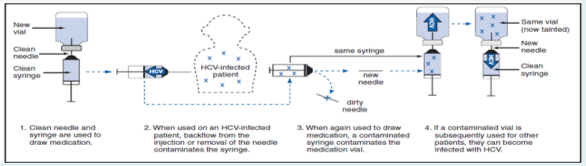
### Single-Patient Use

Most multi-dose injectables will also be used for one patient, one time, then discarded (as above). A limited number of multi-dose injectables (e.g. Actrapid and NovoRapid vials, insulin pens) may be used to prepare and deliver multiple doses, but must be used for **one patient only**.

- On first use, complete label with patient's full name, date of birth, hospital number and date of first use.
- Store in patient-specific location, e.g. patient's trolley drawer (if applicable).
- On administering multi-dose injectables, check the patient identifiers on the product label match the identifiers on the patient's ID band and drug chart, in addition to usual checks.
- Discard on the ward, according to product directions (e.g. 28 days for Actrapid) or as soon as patient no longer requires it.

### Why?

Backflow from the patient occurs on injection, contaminating the drug, syringe, administration set, needle, infusion fluid etc. Outbreaks of blood-borne viruses have occurred[2,3,4] with unsafe injection practices, e.g. below.



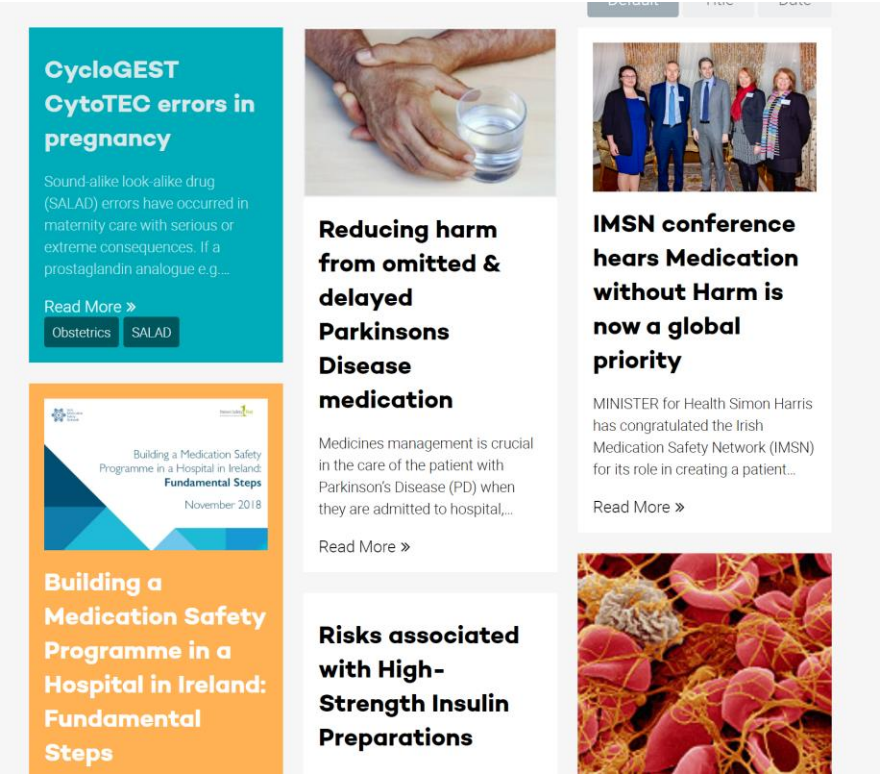

References
1. HSE/HPSC Standard Precautions Version 1.0 April 2009
2. Epi Insight 11(10): Safe Injection Practices Outlined October 2010
3. Centers for Disease Control. MMWR 2008:57(19):513-7
4. Outbreak of Hepatitis C at Outpatient Surgical Centres: Public Health Investigation Report 2009

**Contact Pharmacy, Infection Prevention & Control Team or Nurse Practice Development with queries.**

# Methods

- Remove the hazard
- Forcing functions and constraints – dispensing often lever
- Automate, IT – embed (pump safety software, allergens)
- Standardise, simplify
- Checklists, protocols
- Independent double-checking
- Improve information access – Medicines Guide, IV monographs, IT
- Decrease look-alikes
- Rules and policies
- Education and information - alerts
- Never “try harder”

# Share, spread, support - www.imsn.ie



# A Collaborative Study of Medication Safety in Four Irish hospitals

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## Abstract

Many Irish hospitals have medication safety initiatives in operation. The aims of these initiatives include collecting incident/near miss reports and using what is learned from incidents/near misses to improve systems to promote medication safety. There has been no national co-ordination of these initiatives. Thus, data collection, analysis and system improvements to avoid repetition of incidents is carried out in various ways in various hospitals and learning from incidents has been confined to the individual hospital in which they occur. A medication safety software package, Analyze-ERR®, was obtained from the Institute of Safe Medication Practices, Canada (ISMP Canada). Four Irish hospitals used this software to record and analyse their medication safety data for a three month period. Aggregate analysis of the data was then performed and is summarised in this paper.

## Introduction

Many Irish hospitals have medication safety initiatives in operation. The aims of these initiatives include collecting incident/near miss reports and using what is learned from incidents/near misses to improve systems to promote medication safety. To date, there has been no standardised approach to data collection or data analysis. Aggregate data on medication safety in Ireland has not been published.

Collecting and pooling patient safety information on a national basis is a common and accepted practice. Examples include the Medication Error Reporting Program (MERP) in the USA (run by the United States Pharmacopoeia in association with the Institute for Safe Medication Practices (ISMP)), the National Reporting and Learning System (NRLS) run by the National Patient Safety Agency (NPSA) in the United Kingdom and the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (developed by ISMP Canada, the Canadian Institute for Health Information (CIHI) and Health Canada).

Ireland established enterprise liability under a Clinical Indemnity Scheme (CIS) in 2002 to promote safe patient care, reduce the number of claims and to manage claims in a timely fashion.[1] All enterprises covered by the CIS are required to report all adverse clinical events and near misses on a mandatory basis via a secure web-based Clinical Incident Reporting System, STARSWeb. Medication errors are one category of incidents and near misses that may be reported via STARSWeb. Other risk management incidents/near misses may also be reported, e.g. surgical incidents and infection control incidents. STARSWeb is not currently configured in a format that would have facilitated collecting medication safety data and pooling it for analysis in this pilot study.

A medication safety software package, Analyze-ERR®, was obtained, free of charge, from the Institute of Safe Medication Practices, Canada (ISMP Canada) to facilitate a pilot project to collect and analyse medication safety information in a standardised way in four hospitals in Ireland.

ISMP Canada is an independent Canadian non-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety. Analyze-ERR® is a software documentation tool designed and developed by ISMP Canada for use in institutions to track and analyse medication errors. In Canada, this is followed by a mechanism where users submit data to ISMP Canada, where data are pooled to provide aggregate information on medication errors, e.g. event types, contributory causes. ISMP Canada can then use this data to share the learnings from errors and near misses, including recommendations for prevention of errors, with the healthcare community in Canada.

## Aims

The aims of the study were to:

- **use the Analyze-ERR® software to facilitate standardised medication safety data collection and analysis, and**
- **determine whether this software facilitates pooling of information for greater learning.**

**i Adelaide and Meath Hospital incorporating the National Children's Hospital, Tallaght, Dublin 24**
**ii Mater Private Hospital, Eccles Street, Dublin 7**
**iii Portiuncula Hospital, Ballinasloe, Co Galway**
**iv St. John's Hospital, St. John's Square, Limerick**





## Methods

Analyze-ERR® was installed in each of the four hospitals and used to enter and manage medication safety incident/near miss reports collected from January to March 2006. The hospitals involved in the study were:

- **Adelaide & Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH)** – a public voluntary teaching hospital with six hundred beds
- **Mater Private Hospital, Dublin** – a private hospital with two hundred and two beds
- **Portiuncula Hospital, Galway** – a public general hospital with two hundred and ten beds
- **St. John's Hospital, Limerick** – a public voluntary general hospital with one hundred and three beds

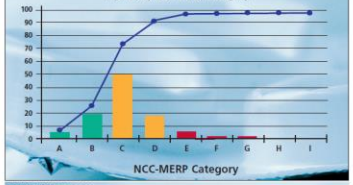
Reports included medication errors, adverse drug reactions and hazardous conditions relating to medication. The data was then sent to the project coordinator for pooling and analysis.

The severity of incidents/near misses was categorised using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) criteria[2] as used on the Analyze-ERR® software (see Fig. 1). In addition to reports regarding medication error, each of the hospitals received reports about adverse drug reactions (ADRs) which did not involve medication error. These reports were also classified into the most pertinent NCC MERP category, i.e. if the ADR resulted in temporary patient harm requiring intervention, it was classified as NCC MERP category E. NCC MERP categories A-B (coloured green in Fig. 1) did not reach the patient, C and D (coloured amber or yellow) reached the patient but did not result in patient harm and categories E-I (coloured red) resulted in increasing levels of patient harm. Harm is defined by NCC MERP as 'Impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom' and corresponds to NCC MERP categories E-I (see Fig. 1).

## Results

Five-hundred and ten (510) medication safety incidents/near misses were recorded (mean 128 reports per hospital, range 14-230). Ninety-three percent of the aggregated incident/near miss reports did not result in patient harm (NCC MERP A-D); 7% or 35 incidents resulted in patient harm (NCC MERP E-I) (Fig. 1).

**FIGURE 1**
**Severity of aggregate incident/near miss reports by NCC-MERP category**




*NCCMERP Categories
A Circumstances or events that have the capacity to cause a medication error.
B A medication error drug event occurred but did not reach the patient.
C A medication error occurred that reached the patient but did not cause patient harm.
D A medication error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
E A medication error occurred that may have contributed to or resulted in temporary patient harm and required intervention.
F A medication error occurred that may have contributed to or resulted in temporary patient harm and required initial or prolonged hospitalization.
G A medication error occurred that may have contributed to or resulted in permanent patient harm.
H A medication error occurred that required intervention necessary to sustain life.
I A medication error occurred that may have contributed to or resulted in the patient's death.

From: US National Co-ordinating Council for Medication Error Reporting and Prevention (NCCMERP) and United States Pharmacopoeia (USP), June 2001





**FIGURE 2**
**Drugs involved in aggr incident/near miss rep**

| Drug (generic) | No. of reports |
|---|---|
| Enoxaparin | 17 |
| Diclofenac | 14 |
| Morphine | 14 |
| Aspirin | 13 |
| Fentanyl | 12 |
| Digoxin | 9 |
| Warfarin | 9 |
| Co-amoxiclav | 8 |
| Insulin | 8 |
| Omeprazole | 8 |

**FIGURE 3**
**Drugs involved in aggr incident reports resulti patient harm (NCC MEI**

| Drug | No. of reports |
|---|---|
| Enoxaparin | 4 |
| Paclitaxel | 3 |
| Amiodarone | 3 |
| Insulin | 2 |
| Moxifloxacin | 2 |
| Zoledronic acid | 2 |
| Aspirin | 2 |
| Clopidogrel | 2 |
| Tetracaine | 2 |

Over 90 drugs were im incident/near miss reports. I diclofenac, morphine, aspirin a resulted in the largest proportio overall. The most frequent dru in reports was enoxaparin, im reports (3.3% of the total) (Fig.

The drugs involved in t proportion of incidents resultin harm (NCC MERP E-I) were (four reports), paclitaxel (three amiodarone (three reports) (Fig three (33) drugs were implicate reports resulting in patient h involved in incidents resulting harm were classified by *Britis Formulary*[3] categories. The mos occurring categories were ca malignancy and immunosuppr anti-infectives. Together, th categories were responsible fo of incidents resulting in patien 4).

The stage(s) in the medi process at which the incident o recorded. An incident/near involve more than one stage patient was prescribed a dru they had a documented allergy and the drug was subsequently administered, the incident/near miss would be entered as both a prescribing and an administration error. Prescribing was responsible for nearly 50% of overall incident/near miss reports (Fig. 5), with administration responsible for nearly 30% and dispensing for

**FIGURE 4**
**British National Formulary[2] categories of drugs involved in aggregate incident reports resulting in patient harm (NCC MERP E-I)**

| BNF Category | No. of Reports | % of Reports |
|---|---|---|
| Cardiovascular | 10 | 21.3 |
| Malignancy, immuno-suppression | 9 | 19.1 |
| Anti-infectives | 7 | 14.9 |
| Endocrine | 5 | 10.6 |
| Anticoagulants | 5 | 10.6 |
| CNS | 3 | 6.4 |
| Anaesthesia | 3 | 6.4 |
| Nutrition and blood | 2 | 4.3 |
| Musculoskeletal and joint | 2 | 4.3 |
| Diagnostics | 1 | 2.1 |

**FIGURE 5**
**Aggregate incident/near miss reports by stage(s) involved (n=510)**


**FIGURE 6**
**Aggregate incident reports resulting in patient harm (NCC MERP E-I) by stage(s) involved (n=35)**

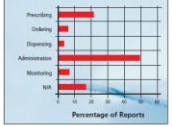
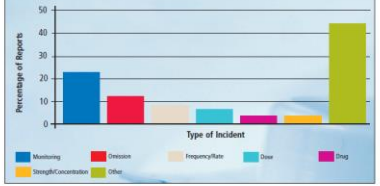







**FIGURE 8**
**Type of incident in aggregate reports resulting in patient harm (NCC MERP E-I) (n=35)**




harm. Dispensing accounted for 10% of the overall figure but just 3% of incidents resulting in patient harm. The way that medication safety incident/near miss data is collected in a hospital can influence these figures significantly. Pharmacy staff are likely to report primarily dispensing and prescribing errors, whereas nursing staff are more likely to report administration errors. In our pilot group, approximately 65% of reports overall were submitted by pharmacy staff and 35% by nursing staff.

The most frequent types of incident reported were wrong dose, wrong frequency/rate and dose omission. Wrong dose could involve error at the prescribing, ordering, dispensing or administration stages. Wrong frequency/rate and dose omission could involve prescribing or administration. However, it is interesting to note that of those incidents resulting in patient harm, the 'monitoring' category accounted for over 20% of incidents. Many of these incidents involved allergic reactions, i.e. a medication that the patient was allergic to was prescribed and administered, resulting in an allergic reaction to the patient. In addition, this category included situations where patient factors were not taken into consideration when prescribing and/or administering drugs, e.g. there was a contra-indication or caution to the use of the drug in that patient or a drug-drug interaction.

The pilot was conducted over a very short time period and with limited resources. Comparison of the pilot data with published data from other countries was not carried out at this stage. It is clear that further collection and analysis of Irish medication safety information would be useful to identify trends and issues requiring attention.

Following the pilot project, feedback has been given to ISMP Canada. Overall, the pilot group found Analyze-ERR® very helpful for collecting and analysing their medication safety data and will continue to use it for this purpose. The pilot group were pleased to be able to share medication safety information with their colleagues. A number of issues were raised which ISMP Canada feel could be addressed should the pilot lead to a more permanent solution for Ireland. These include the need to adapt the database to the Irish medication use system and to incorporate information on adverse drug reactions.

For Analyze-ERR® to function optimally in the Irish setting, a central Irish Analyze-ERR® database is needed. This means that each institution would send their anonymised data to the central database, thus compiling Irish data. The individual hospitals could then compare their data to the overall Irish data. The value of such comparisons would include reassurance locally that the data collected is 'normal' or valid data. In addition, it could be used to identify when local data is out of line with general trends, e.g. if data is being entered under different categories by different participants, whether the professions reporting lead to more of particular types of reports, whether the participating organisation is identifying a high or low proportion of incidents resulting in harm (and that if the number is very low, whether some important information is being missed by the reporting system). In addition to the advantages to individual hospitals, having reliable, internationally comparable statistics on medication safety events would be of great value to the Irish health system.

The pilot group has presented to the State Claims Agency, which operates the Clinical Indemnity Scheme (CIS). Currently, medication safety incidents/near misses need to be entered by organisations indemnified by the CIS to STARSWeb in addition to Analyze-ERR®. The CIS is investigating ways of improving the quality of medication safety information available to them and is liaising with the pilot group to facilitate this.

## Conclusion

Using a standardised, medication safety-specific database to record medication safety incident/near miss data facilitated aggregate analysis. Standardising the medication safety data collected by hospitals and having an appropriately resourced facility to house a central database would facilitate analysis of medication safety data for Ireland and comparison with international information.

## Acknowledgements

The pilot group would like to acknowledge David U, Robert Lam and colleagues in ISMP Canada for providing us with the Analzye-ERR® software and user support.

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2 National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) criteria. Available from http://www.nccmerp.org (last accessed 18/12/2006)
3 British National Formulary, 51st Edition, March 2006, British Medical Association, Royal Pharmaceutical Society of Great Britain

# Hospital

- Six Sigma (DMAIC) process improvement
- Institute for Healthcare Improvement www.ihi.org
  - Model for Improvement
- Move the big dots – mortality, morbidity – 100,000 lives campaign, saving 500,000 lives from harm
- Reframed goal – reduce harm

# Using Six Sigma to improve once daily gentamicin dosing and therapeutic drug monitoring performance

Sean Egan,[1] Philip G Murphy,[2,3] Jerome P Fennell,[2] Sir Carolyn McLean,[5] Muriel Pate,[1] Ciara Kirke,[1] Annette W Eddie McCullagh,[2] Joan Murphy,[6] Tim Delaney[1]

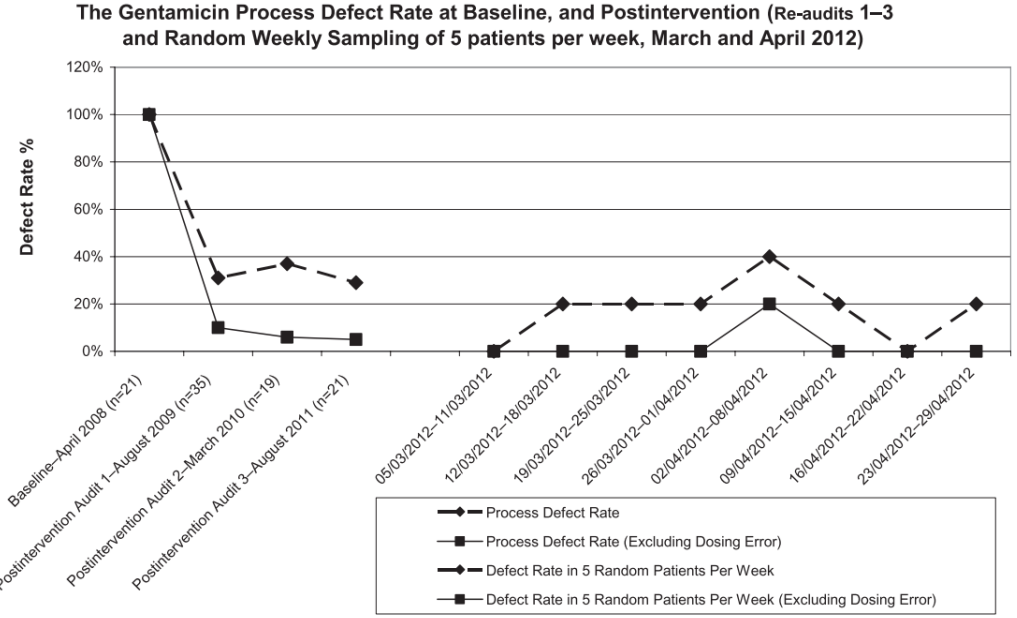
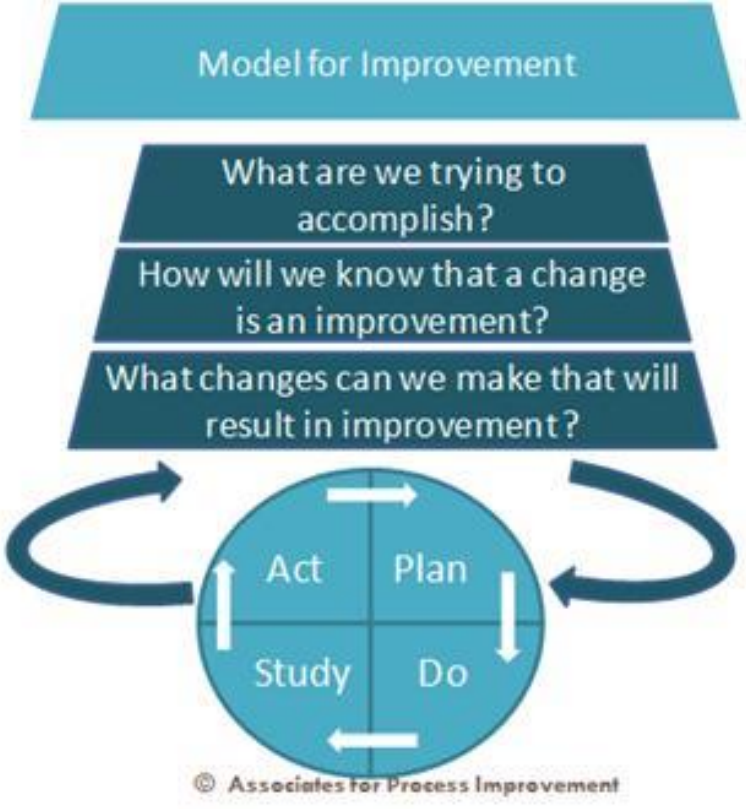



**Figure 3** The gentamicin dosing and monitoring process defect rate as per critical to quality parameters and baseline and at each postintervention audit point, and over an 8-week period postintervention.

# Quality improvement



# Preventing perioperative DKA

- Aim: preventing perioperative DKA
- Changes: simplified algorithm, no GKI (glucose-potassium-insulin infusion)–IV insulin syringe driver and IV fluids via Volumetric pump, Y site cannula, standardised fluid 4.5% NaCl / 5% glucose / 10 mmol KCl in 500 mL, new chart
- Rapid cycle testing and improving essential
- Results: no perioperative DKA (from 1 per month or 2); less than halved hypoglycaemia

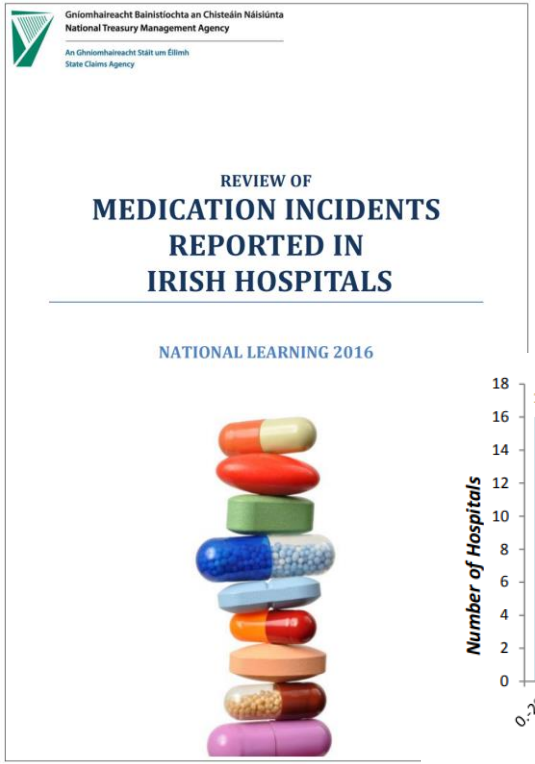
# How do we improve?

- Follow guidance (best practice, patient safety)
- Risk identification – external + internal
  - Measurement for improvement
  - Audit and research
  - Incident reporting and analysis
  - Complaints, coroner's cases, claims, morbidity & mortality
  - Risk assessment and risk registers, Failure Modes & Effects Analysis (FMEA)
- Analysis
- Prioritise – harm, resources
- Improve – with staff, quality improvement methodology

# National learning and improvement



# National: www.stateclaims.ie




| Medication Name | Extreme | Major | Moderate | Minor | Negligible | Total |
|---|---|---|---|---|---|---|
| Enoxaparin sodium | 1 | | 2 | | 142 | **145** |
| Amoxicillin \|\| clavulanic acid | | | 11 | 2 | 108 | **121** |
| Paracetamol | 1 | | 4 | 2 | 111 | **118** |
| Morphine sulphate | | | 9 | 4 | 93 | **106** |
| Vancomycin | | | 5 | 3 | 85 | **93** |
| Oxycodone | | | 5 | 4 | 80 | **89** |
| Gentamicin | | | 14 | 3 | 71 | **88** |
| Heparin | 1 | | 5 | 1 | 79 | **86** |
| Warfarin sodium | | 1 | 1 | 1 | 80 | **83** |
| Piperacillin \|\| Tazobactam | | | 6 | 5 | 63 | **74** |
| Benzylpenicillin sodium | | | 8 | | 59 | **67** |
| Apixaban | | | 2 | 1 | 63 | **66** |
| Diclofenac | | | 5 | 2 | 53 | **60** |
| Insulin aspart | | | 1 | 1 | 47 | **49** |
| Fentanyl | | | 4 | 2 | 39 | **45** |
| Rivaroxaban | | | 3 | 1 | 41 | **45** |
| Tinzaparin | | | 3 | | 40 | **43** |
| Methotrexate | | | 2 | | 41 | **43** |
| Furosemide | | | 1 | | 40 | **41** |
| Acetylsalicylic acid (Aspirin) | | | | | 38 | **38** |

Table 4: Twenty most common medications involved in incidents reported in acute hospitals, 2016

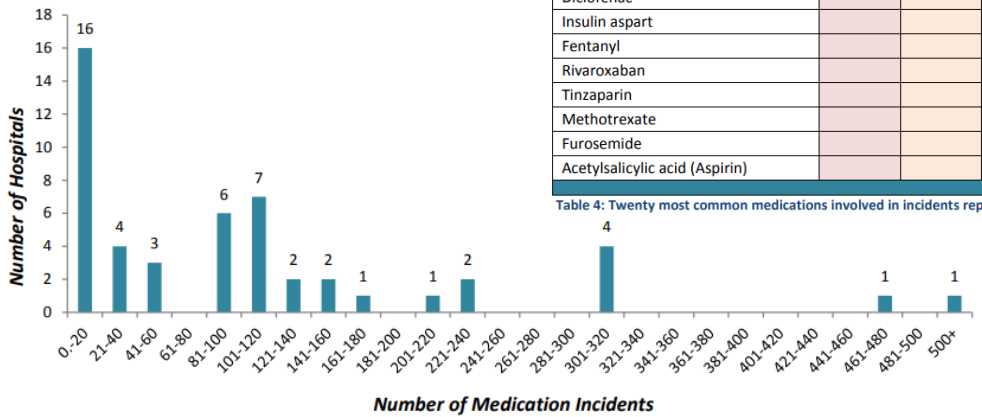



Figure 2: Distribution of medication incidents reported from 50 acute hospitals, 2016

# Recommendations

## 5. Areas of Risk

### Anticoagulant Prescribing

Detailed analysis of incidents involving anticoagul
preventable errors occurred during 2016:

- Inappropriate dosing of Low Molecular V
  Anticoagulants (DOACs) in specific popul
  renal function.
- Therapeutic duplication through co-pres
  increased risk of bleeding.
- Omission of regular anticoagulants on di
  thromboembolism.

M

- Medical and nursing staff familiarise the
  ensure name recognition when prescrib
  anticoagulants, inducers/inhibitors of th
  glycoprotein (P-gp).
- Continued education regarding the neec
  such as older persons and those with re
- Patients are counselled regularly regard
  risks involved in their use to ensure vigilance when admitted for acute care.
- Front line staff utilise Clinical Pharmacy services when starting medications that they are unfamiliar with.

A high rate of incident reporting is considered a marker of a strong patient safety culture. It is hoped that continued uptake of the National Incident Management System (NIMS) will facilitate both the SCA and the healthcare system to ensure that widespread learning occurs in response to incidents in all areas. This is especially important for medication errors which have a widespread impact on patient safety and quality of care, both nationally and internationally.

To mitigate risk regarding medication incidents, it is of utmost importance that Clinical Pharmacy services be made available, not only to identify, report and disseminate learning from incidents, but to add medication expertise to multi-disciplinary teams in clinical settings. International data shows that the clinical pharmacist is a crucial part of the health care team contributing to increased quality of care at the least expense whilst minimising preventable patient harm.[9]

Further overall measures for the prevention of medication incidents identified in a recent SCA report[4] included:

- Medication Reconciliation at the time of patient transfer.
- Implementation of a medication safety training and education programme for doctors and nurses with audited outcomes.
- Implementation of the Electronic Healthcare Record with Clinical Decision Support and Computerised Physician Order Entry.
- Introduction of a national drug kardex in all hospitals and healthcare services.

### Use of Antibiotics with Narrow Therapeutic Indexes

Gentamicin and Vancomycin were prominent in the ten most common medications causing incidents, with
ibiotics. Sub-optimal dosing can
istance. Over-dosage can lead to
nce. These medications are both
used to treat an estimated
d:

ients with unstable kidney
on

**Penicillin Allergy**

Penicillin-based antibiotics accounted for 41.7% of all antibiotic consumption in hospitals in Ireland[6], which, when combined with a significant cohort of patients who self-report penicillin allergy, represents an area of considerable risk in the Irish health system.

In 2016, there were 283 incidents relating to penicillin-based antibiotics, 30 of which caused harm and 48 of which related to their use being contra-indicated, mostly by allergy. These incidents represent preventable patient harm and an opportunity to enhance patient safety.

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Medication Incidents Reported In Irish Hospitals, 2016 | 7

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**Recommendations**

- The importance of education around, and compliance with, HSE policy on Healthcare Records Management[8], particularly in relation to the requirement to record allergy status accurately is reinforced.
- Clinical Pharmacy services, where available, are utilised on medical rounds.
- Patients are educated regarding the presence and severity of their allergy status and the medications which correspond to that allergy status.
- Care is taken to prescribe medications by generic name, rather than brand name, as name recognition can act as an important safety net in these cases.

# www.hiqa.ie




## Key recommendations

Key recommendations from HIQA medication management monitoring programme are listed below. They are separated into recommendations with a national focus and those focused on improving medication safety in hospitals.

**Recommendations focused on improving medication safety at a national level**

1. At a national level, efforts to enhance learning from medication incidents and quality improvement initiatives should be put in place. This should include reviewing research in relation to medication safety, both nationally and internationally, to proactively address medication related risk.
2. Centralised arrangements should be put in place to ensure good practices that HIQA has reported through these series of inspection are shared.
3. A national plan for the development of comprehensive clinical pharmacy services that sets out the desired model of care, and the appropriate resources to ensure consistency across hospitals should be developed.
4. Develop a national approach to advance medication reconciliation to include defining responsibility for medication reconciliation and using electronic solutions to reduce time spent by clinical staff on medication reconciliation.
5. Utilise information technologies such as ePrescribing, smart pump technology and decision support tools to reduce medication incidents and risks. At a national level hospital groups should work together to commence the implementation of electronic solutions to improve medication safety.

**Recommendations focused on improving medication safety in hospitals**

6. Hospitals must have formalised governance structures with clear accountability and responsibility arrangements to support medication safety. This includes a functioning Drugs and Therapeutic Committee with clear terms of reference and membership to provide assurance that medication management systems are safe.
7. The Drugs and Therapeutics Committee should have a clear strategic plan for improving medication safety outlining short, medium and long-term goals, with a supporting time bound medication safety programme or plan.



Medication safety monitoring programme overview report
Health Information and Quality Authority

8. Hospitals should have a defined formulary process to outline medicines that are approved for use in the hospital, and provide information and standard guidance on the use of these medicines.
9. Hospitals should build patient education requirements into the medication management process, based on services provided and their patient population, to ensure patients and or care givers are given the appropriate medicines-related information.
10. Hospitals should provide clinical staff with easily accessible information and or policies, procedures, guidelines and or protocols to guide the safe use of medicines at the point of prescribing, preparation and administration.
11. Hospitals should support a culture of reporting medication related incidents and near misses among all healthcare professionals. Data from medication incidents should be routinely analysed to identify trends or patterns in relation to risk and identify areas that require targeted improvement.
12. Hospitals must ensure healthcare professionals have the necessary competencies to deliver high-quality medication safety through induction and ongoing training. This should include a structured, targeted programme of education for medication safety aligned with the hospitals medication safety strategy.

# National Medication Safety Programme

- www.safermeds.ie
- Work with patients, healthcare professionals and organisations to reduce medication-related harm

# Patients at greater risk of harm...
# ...and the priorities for improvement

- Number of medications (inappropriate polypharmacy)
- Transitions of care
- High-risk medication (A PINCH)
  - Antimicrobials, Potassium/electrolytes IV, Insulins, Narcotics (opioids), Chemotherapy including methotrexate, Heparins and anticoagulants; plus Diuretics?, NSAIDs?
- High-risk patients (e.g. renal impairment)


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BEFORE
YOU TAKE IT...
KNOW
your medicines
and keep a list
CHECK
that you are using
the right medicine
the right way
ASK
your healthcare
professional if
you're unsure


BEFORE
YOU GIVE IT...
KNOW
your medication
CHECK
you have the right
☑ patient
☑ medicine
☑ route
☑ dose
☑ time
ASK
your patient
if they understand

# Know Check Ask & List

### What is My Medicines List?

My Medicines List is a list of all the medicines and supplements you take.

### Why should I use it?

Keeping an up to date list can help you know your medicines. It can also enable you when discussing your medicines with a healthcare professional.

### How should I fill it in?

To fill out My Medicines List, you need all your medicines in front of you. Another option is to ask your pharmacist to print out a list for you. Make sure you include all prescribed and over-the-counter medicines and supplements.

### How should I use it?

Keep your list up to date. Bring it with you when attending any healthcare appointment. You may find it useful to keep a photo of this list on your phone.

### How can I get another form?

To get another copy you can print from www.safermeds.ie or ask at your local pharmacy.


## MY MEDICINES

| | | |
|---|---|---|
| Emergency Contact Name/phone number | | |
| Name/Date of Birth | My allergies and how I react | |
| My pharmacy name/phone number | My family doctor name/phone number | Date I filled out this form |

| Name of Medicine | The strength | How much I take each time | I take it | I take it every day (Yes / No) | Why I take it? | My notes |
|---|---|---|---|---|---|---|
| **Example:** ABC Tablets | 25mg | 2 tablets | Twice a day morning & night | Yes | For my heart | Blue oval tablet, with food |
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www.safermeds.ie

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