

Practical experiences of risk minimisation

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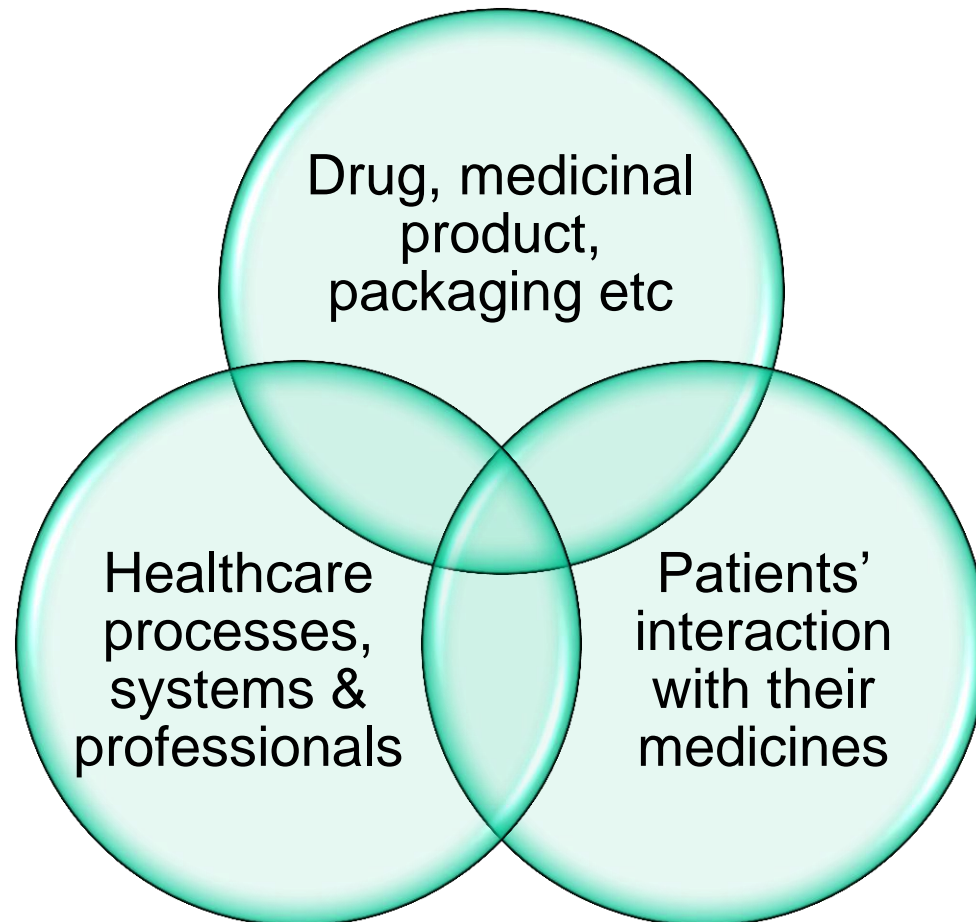
16th September, 2015



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Sources of harm with medicines



Burden of medication-related harm

- Adverse reactions (including preventable ADRs) in 6.1-9.2% of hospital patients
- Prolonged hospitalisation 1.2-8.5 days/ adverse reaction/ patient
- Serious adverse reactions in 4%; older patients 11.9%
- Number of drugs (polypharmacy), renal impairment, high-risk medication most predictive of risk of harm

Saedder et al. Br J Clin Pharmacol 2015

de Vries EN, et al. Qual Saf Health Care 2008; 17: 216-23

Krahenbuhl-Melcher A et al. Drug Saf 2007; 30: 379-407

Muehlberger N et al. Pharmacoepidemiol Drug Saf 1997; 6 Suppl 3: S71-7

Tegether I et al. Br J Clin Pharmacol 1999; 47: 557-64

Hakkarainen KM et al. PLoS One 2012; 7: e33236

Kongkaew C et al. Ann Pharmacother 2008; 42: 1017-25

Lazarou J, Pomeranz BH, Corey PN. JAMA 1998; 279: 1200-5

Rodriguez-Monguio R et al Pharmacoeconomics 2003; 21: 623-50

Beijer HJ et al. Pharm World Sci 2002; 24: 46-54

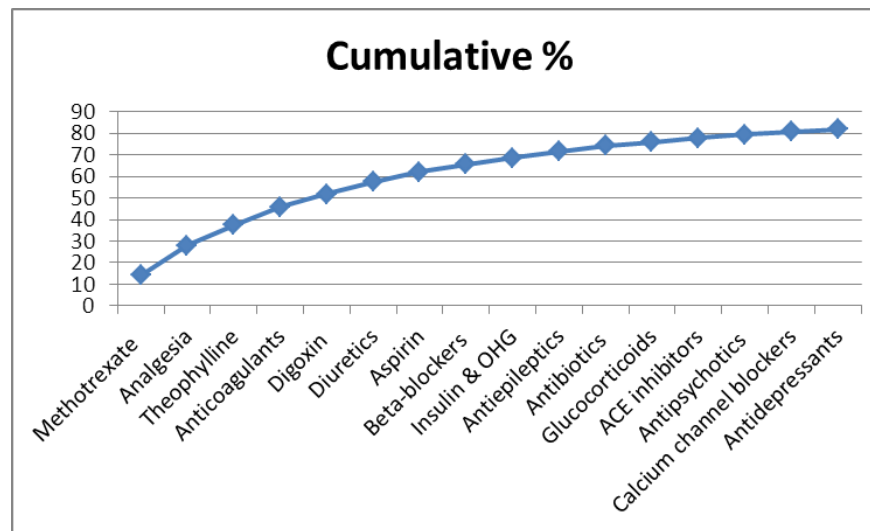


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High-risk medication/classes

- Most drug-related harm with, e.g., anticoagulants, opioids, NSAIDs, antimicrobials, insulin, diuretics
- 70% of preventable death or serious adverse drug reactions (ADRs) due to nine drugs or classes

Saedder EA et al. Eur J Clin Pharmacol 2014 70:637–645



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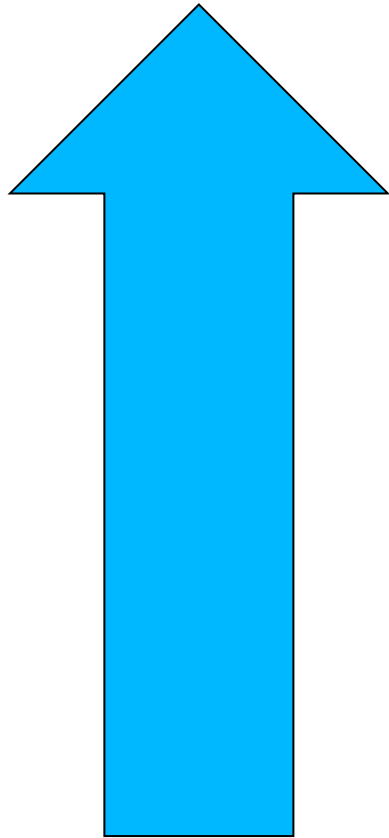


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Prevention is better than cure

- Minimising potential risks and avoiding error
- Understand drug, product, device AND processes, psychology, human factors
- Healthcare professional participation in EMA
 - Consultations
 - Naming Review Group
- Packaging, labelling
- Patient/ HCP information
- Restrictions

Hierarchy of effectiveness



Remove the hazard
Forcing functions and constraints
Automation and computerisation
Standardisation, simplification
Checklists and double-checking
Rules and policies
Education and information
“Try harder”

Patient needs 5,000 unit bolus, what do you give?



Total content eliminated error



Minimising risk in hospitals

- Risk identification
 - Local reporting, national and international alerts, research...
- Risk analysis
 - Systems analysis of serious incidents and trends
 - Screening alerts
- Prioritising for action
 - Potential for patient harm, potential improvements
- Minimising risk
 - Information, alerting appropriate staff
 - Process improvement, systems improvement

Local alert

- Acute kidney injury with aciclovir IV
- Report to pharmacovigilance and indemnifiers
- Open communication with patients
- Incident review - ideal body weight, hydration
- Review evidence, expert opinion nephrology/ neurology/ microbiology/ pharmacy
- Local prescribing guidance and IV monographs changed, memo/alert circulated
- Vigilance and reporting

International alert

30 March 2012

DHPC agreed by PRAC on 9 October 2014

21st November 2014

Direct Healthcare Professional Communication Stelara® (Ustekinumab) solution for injection in pre-filled syringe Risk of exfoliative dermatitis and skin exfoliation

Dear Healthcare professional,

Janssen, in cooperation with the European Medicines Agency (EMA) and the Health Products Regulatory Authority (HPRA), would like to inform you of the following:

- Cases of exfoliative dermatitis have been reported, although rarely, in psoriasis patients receiving ustekinumab. Skin exfoliation without other symptoms of exfoliative dermatitis has also been reported.
- Be alert for symptoms of exfoliative dermatitis in patients receiving ustekinumab. The symptoms of exfoliative dermatitis may be indistinguishable from erythrodermic psoriasis. Patients with plaque psoriasis may develop erythrodermic psoriasis as part of the natural course of their disease.
- If a patient develops these symptoms, start appropriate therapy promptly. Stop ustekinumab treatment if you suspect these symptoms to have been caused by a

Direct Healthcare Professional Communication – New contraindications for strontium ranelate (Protelos)

Dear Healthcare Professional,

This letter is to inform you of new contraindications for strontium ranelate (Protelos) and is sent in agreement with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Summary:

Protelos is now contraindicated in patients with:

- **current or previous venous thromboembolic events (VTE), including deep vein thrombosis and pulmonary embolism;**
- **temporary or permanent immobilisation due to e.g. post-surgical recovery or prolonged bed rest.**

Further information on the safety concern

Protelos (strontium ranelate) is authorised for the treatment of osteoporosis in postmenopausal women to reduce the risk of vertebral and hip fractures.

A European review was initiated following publication of a study in France¹ where 199 severe

Local implementation

- Recommendations – patient group, ADR or risk, potential severity
- Improvement
 - Awareness – who needs to know? Patients? Which specialties, professions?
 - Urgency, type of communication?
 - Embed into processes, reference sources
 - Change systems, behaviour
 - Measure to ensure implemented
 - Outcome measures to ensure effective

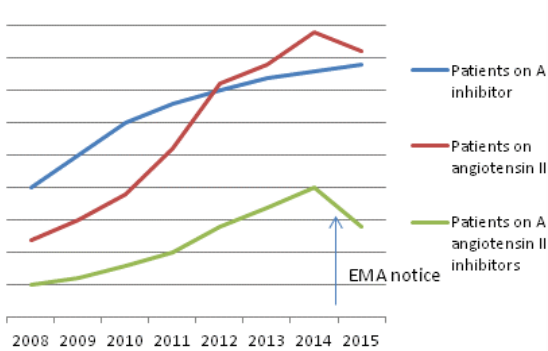
Actions to outcome



23 May 2014
EMA/294911/2014

Combined use of medicines affecting the renin-angiotensin system (RAS) to be restricted – CHMP endorses PRAC recommendati

The European Medicines Agency's Committee for Med endorsed restrictions on combining different classes

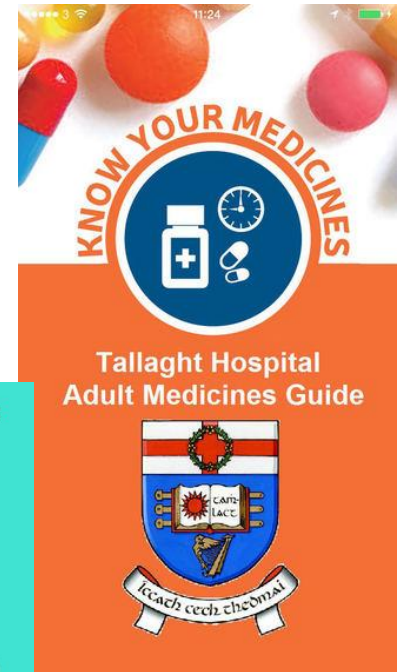


March 2015 – September 2015

BNF 69

The authority on the selection and use of medicines

bnf.org



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Healthcare professionals and EMA

- Working together to combine regulatory and pharmacovigilance knowledge with understanding of processes, psychology and human factors
- Prevention better than cure

Contact



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