Key Causes of Medication Errors and Strategies for Improvement

WHO Global Challenge on Medication Safety
Bonn Germany
March 29, 2017

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www.ismp.org
Institute for Safe Medication Practices

• A Not-for Profit Charity (501c3)
  – multi-disciplinary (pharmacists, nurses, physicians)
• Interacts with but independent of regulatory, standard setting, or accrediting organization
• Relies on healthcare professionals and consumers to supply information on medication errors (ISMP National Medication Errors Reporting Program – MERP)
• Mission: To advance patient safety worldwide by empowering the healthcare community, including consumers, to prevent medication errors
WHO Global Challenge on Medication Safety

• “Many countries lack data about medication safety...
• “High-income countries are more likely to possess robust medication safety systems...However, errors still occur...indicating that focused efforts...may diminish the threat”
• “Systems approach is needed to build a safety net to catch errors before they reach the patient...rather than solely relying on the actions of individuals”
What We are Hearing from Others

- Need for accurate medication histories/lists to improve medication reconciliation at all transitions of care
- Need to focus efforts on high risk patients and high-alert medications
- Issues with polypharmacy
- Need for better and authorized patient information/education
- Listen to and involve the patient
Other Key Causes of Medication Errors

- Similar medication –
  - Nomenclature, Labeling/Packaging
- Ambiguous display of concentration or strength
- Lack of warnings on ampules'/vials
- Unavailability of pre-mixed medications for intravenous use leading to preparation of medications by nurses
- Lack of universal bar codes
- Lack of Harmonization within countries and internationally
- Lack of medication safety ‘advocates’
US
US
Spain

Benadon

Piridoxina
300 mg/2 ml

Benerva

Tiamina
100 mg / 1 ml

Roche

6 ampollas de 2 ml

ISMP

INSTITUTE FOR SAFE MEDICATION PRACTICES
Latin America - Colombia
US
Vaccine Error in Brasil
One of these things is not like the others...

Making a serious drug error shouldn’t be this easy.
Spain
Canada
France
US
irinotecan hydrochloride injection

20 mg/mL
(on basis of trihydrate)

Caution: Federal law prohibits dispensing without prescription.

Warning: For intravenous use only—must be diluted before use.

Pharmacia & Upjohn

irinotecan hydrochloride injection

100 mg/5 mL
(20 mg/mL)

— on basis of trihydrate

Caution: Federal law prohibits dispensing without prescription.

Warning: For intravenous use only—must be diluted before use.

Pharmacia & Upjohn
Outsourcing in the US
Malaysia and Saudi Arabia
Unsafe Products
15 Syrian children die after measles vaccinations

BEIRUT — At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government air strikes on a central city climbed to nearly 50, a heavy toll even by the vicious standards of the country’s civil war, activists said.

The children, some just babies, all exhibited signs of “severe allergic shock” about an hour after they were given a second round of measles vaccinations in Idlib province on Tuesday, with many suffocating to death as their bodies swelled, said physician Abdullah Ajaj, who administered the vaccinations in a medical center in the town of Jarjanaz.
Vaccine Diluent Packaging
Neuromuscular Blocking Agents Spain
Neuromuscular Blocking Agents New Zealand
United States Pharmacopeia (USP)
Chapter 31

Neuromuscular Blocking and Paralyzing Agents

• All injectable preparations of neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules or cap overseals. Both the container cap ferrule and the cap overseal must bear in black or white print (whichever provides the greatest color contrast with the ferrule or cap color) the words: “Warning: Paralyzing Agent” or “Paralyzing Agent” (depending on the size of the closure system). Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the closure ferrule.
With Warnings
Regulatory Achievements on an International Scale
Regulatory Improvements

- **FDA/US — April 2016**
  - Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

- **Health Canada — June 2016**
  - Good Label and Package Practices Guide for Prescription Drugs and Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products
Regulatory Improvements

• Council of Europe – June 2016
  ➢ Resolution on good reconstitution practices in health care establishments for medicinal products for parenteral use and
  ➢ Resolution on the quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients
Regulatory Improvements

• European Medicines Agency (EMA) – June 2016
  Described the key concepts of the European Unit good practice guidance for defining, classifying, coding, reporting, evaluating and preventing medication errors.

A guide to the graphic design of medication packaging

Second edition
Guidance for Industry

Best Practices in Developing Proprietary Names for Drugs

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov/. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact (CDER) Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Kellie Taylor at 301-796-0157, or (CBER) Office of Communications, Outreach and Development at 800-835-4709 or 240-402-7600.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2014
Drug Safety

Guidance for Industry

Safety Considerations for Product Design to Minimize Medication Errors

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2012
Drug Safety
Still Work to be Done
IMSN Global Regulatory Meeting
Toronto October, 2016

• Meet with regulators to share their views and concerns on labelling, packaging and nomenclature issues prone to medication errors and to further establish a consensus on a shared action plan for improving medication safety at the global level in coordination with the WHO Global Challenge on Medication Safety.
Additional Efforts

• Regulatory, Government, and Industry interventions
  – Universal bar codes
  – Harmonization of labelling/packaging and the availability of ready to use products
• Improving regulatory agencies and industry efforts prior to the marketing authorization
• Raising awareness and learning from medication errors reporting programs and pharmacovigilance efforts in all countries
• Medication Safety Champions/Medication Safety Officers in hospitals and/or at a country level to help disseminate learnings from other countries