Medication without harm: is there a role for improvement science?

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Improvement science

Provider
Improvement science research can show which are the most promising solutions.
Research could also demonstrate if they are cost effective.

Improvement science is about understanding how solutions work, in what context and how to adapt for new settings.

Communities/ ... and individuals...

Policy ecosystem
Builds on Deming’s system of profound knowledge

- Knowledge or appreciation of the system
- Knowledge and understanding of variation
- Knowledge of how knowledge grows (theory of knowledge)
- Knowledge and understanding of psychology
Seven Propositions of the Science of Improvement: Exploring Foundations

Rocco J. Perla, EdD; Lloyd P. Provost, MS; Gareth J. Parry, PhD

- Grounded in testing and learning cycles
- Conceptualistic pragmatism
- Combination of psychology and logic
- Considers contexts of justification and discovery
- Requires the use of operational definitions
- Employs Shewhart's theory of cause systems
- Informed by systems theory
Organisationally-based initiatives

PDSA cycles

Lean Business Process Re-engineering

Business Process Re-engineering

Traditional professional initiatives

Audit

Guidelines

Peer review

Governmental approaches

Regulation

Performance management

Legislation

Economic approaches

Competition

Financial incentives

Choice
Any area that contributes better knowledge and understanding of the safe and effective use of medicines, pre- and post-marketing

the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
Look alike: Sound-alike medicines

Causes
- Weak systems
- Human factors

4 areas
- Patients and public
- Medicines
- Healthcare professionals
- Systems and practices
The Report of the Short Life Working Group on reducing medication-related harm

Key Priorities

- Work with industry and MHRA to produce more patient friendly packaging and labelling.

- Work with pharmacy dispensing computer system suppliers to ensure that labelling contributes to safer use of medicines and does not hinder, for example by labels being stuck over packaging or by using unfamiliar language.

- Build on work to identify and increase awareness of ‘look alike sound alike’ drugs and develop solutions to prevent these being introduced.
18 November 2015
EMA/606103/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Good practice guide on risk minimisation and prevention of medication errors
Final

6.1.1.2

However, in line with other guidance [...] it is emphasised that the use of **colour-coding is not usually recommended** given the limited range of available colours and the absence of common understanding of colour coding conventions.

Different MAHs and applicants make use of colour as part of their brand and livery and in most cases there is **no set colour scheme that must be used for a given indication or class of medicinal products**. However, choice of colour should be considered in product design to ensure that it does **not introduce the risk of confusion** with other established products where formally-agreed colour conventions exists (e.g. in some Member States, asthma reliever inhalers have blue-coloured dust caps while maintenance corticosteroid inhalers have red or brown dust caps).
Does Tall Man lettering prevent drug name confusion errors? Incomplete and conflicting evidence suggest need for definitive study

Bruce L Lambert, 1 Scott R Schroeder, 2 William L Galanter 3

Responding to the challenge of look-alike, sound-alike drug names

P L Trbovich, 1,2,3 Sylvia Hyland 4

https://qualitysafety.bmj.com/content/qhc/25/4/213.full.pdf
https://qualitysafety.bmj.com/content/qhc/26/5/357.full.pdf
Preventable Medication Errors – Look-alike/Sound-alike Drug Names

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Preventable Medication Errors – Look-alike/Sound-alike Drug Names

• Multi-incident analysis of medication incidents

• Hierarchy of effectiveness for prevention

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Go to www.menti.com and use the code 81 27 99

What 3 strategies would you implement to reduce look-alike, sound-alike errors?

https://www.mentimeter.com/s/b1a3a38dbf2d6bf64a7ab506caba15c/fec5b416f79f
Themes and contributory factors

- Individual factors
- Environmental factors
- Technological factors
- Unique factors (related to the look or sound alike medicine)

A physician wrote a prescription for Hydrocortisone 1% in Mycostatin®, however, Hydrocortisone 1% in Miconazole (Monistat®) was filled. The pharmacy staff member thought Mycostatin® and Miconazole were the same thing.

A pregnant patient was prescribed Diclectin®, but Dicetel® was filled. The patient had been on Dicetel® many times in the past.

A patient was prescribed Carbamazepine CR 200mg, but Carbamazepine 200mg was dispensed.

Solutions - Hierarchy of effectiveness

**Stronger Actions**
- Change cultural approach
- Architectural / physical plant or equipment changes
- **Standardise** and usability testing of equipment or care plans
- **Simplify** the process and remove unnecessary steps

**Moderately Strong Actions**
- Effective use of skill mix
- Eliminate look and sound-a-likes
- Eliminate / reduce distractions
- Checklist / cognitive aids

**Weaker Actions**
- Double checks
- Warnings and labels
- New procedure / policy
- Re-training focused on an individual not cohort

From: C Lee, K Hirschler. How to make the most of actions and outcomes
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Now for a different example…. 
Transition to the Use of Dolutegravir

- **Dolutegravir (DTG):** Integrase inhibitor indicated for the treatment of HIV in combination with other antiretrovirals
  - Fixed dose combination likely to be average price of US$ 75 per patient per year
  - Efficacy: High genetic barrier to resistance
Dolutegravir Roll Out in Kenya

- In June 2017 Kenya National AIDS and STI Control Programme (NASCOP) initiated DTG roll out to select programs
- Concerns about DTG utilization in the population:
  1. Lack of ADR data in a sub Saharan African population
  2. Use in high TB burden country – due to drug-drug interactions and immune reconstitution syndrome
- AMPATH is an antiretroviral sentinel surveillance site in Kenya
Pharmacovigilance in LMICs

Go to www.menti.com and use the code 81 27 99

- What do you believe the challenges are for ADR detection and reporting in low and middle income settings? (Rank the following options)

1. Capacity of the National Regulatory Authority
2. Clinician attitudes – unwilling or uncomfortable reporting ADRs
3. Low numbers of health care providers
4. Lack of public knowledge
5. Lack of systematic patient records
6. Self medication or use of traditional healers
You are asked to develop a pharmacovigilance program for the DTG roll out at 4 high patient volume sites at AMPATH. Your resources include:

- Electronic medical record ADR reporting system
- Clinical officers
- Peers
- Pharmacist
- Patient ADR call center

You have 100 points which represent resources (time, training, funding, etc.) to allot to the above options. How do you model your program?
Total number of patients 5063
- 4 pilot sites: 3600
- 34% male, 66% female
- 75 patients on anti-tuberculosis medications
- 35 pregnant patients utilizing DTG
  - 4 in the first trimester
  - 13 in the second trimester
  - 16 in the third trimester
- 10% of patients reported an ADR to a peer

Strategy utilized in ADR detection and reporting:
- 2 trained HIV peers at largest site
- Inclusion of mandatory side effects question in electronic medication records

Outcome data on patients is pending
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