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Medication safety incidents reported to the National Reporting and Learning system in England and Wales: A review of primary care incidents classified as severe harm and death

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Focal Points

- This study aimed to describe the nature, range and severity of medication-related patient safety incidents in primary care with severe harm or death outcomes.
- Prescribing incidents are the greatest cause of medication-related deaths, although more dispensing incidents are reported.
- Misclassification of harm severity was a common finding.
- The quality of incident reports are variable and consideration needs to be given to enhance the quality of reporting to allow improved learning.

Introduction

In 2003 the NRLS was created to learn from patient safety incidents occurring to NHS funded patients in England and Wales. The NRLS is the most comprehensive patient safety incident reporting system in the world.[1] Medication errors are a major cause of unsafe primary care. There has been limited research to understand medication errors reported by healthcare professionals in community settings.[1]

Aim

The aim of this study was to describe the nature, range and severity of medication incidents occurring in primary care reported to the NRLS with an outcome severity of severe harm and death.

Methods

Study design

Cross-sectional study of incident reports.

Sampling

All reports described in the NRLS as medication errors that occurred in primary care and resulted in severe harm or death outcomes for patients were identified from 272,000 incident reports between 2003 – 2013.

Data classification

Free-text entries were read and coded using the PISA Classification System. Steps undertaken during data processing and classification are overviewed in Figure 1.

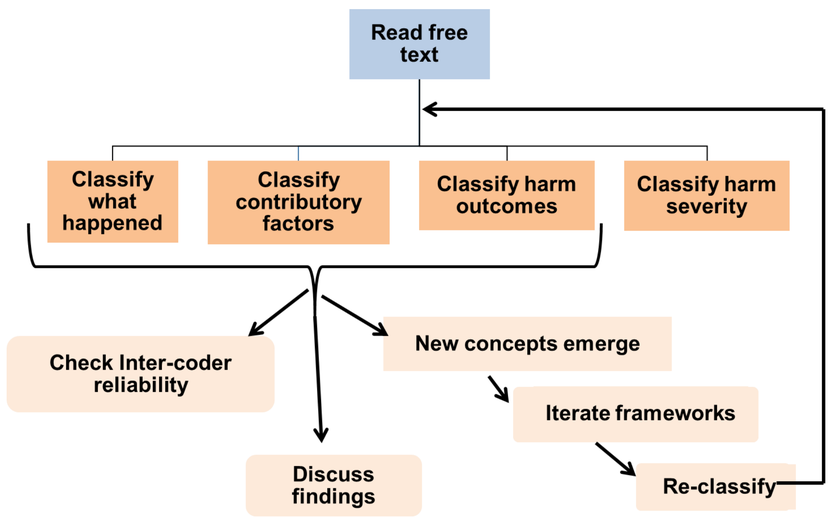
Data analysis

Exploratory data analysis was undertaken to identify the most frequent incident types.

Ethics

The Aneurin Bevan University Health Board Risk Review Committee waivered the need for ethical review.

Figure 1. Data classification



Results

- 271 incident reports were identified, 226 incidents were categorised as severe harm and 45 as death.
- Incident reports varied in length and detail (see box 1 for example of incidents causing severe harm or death).
- 40 (18%) and 9 (20%) of severe and death incidents respectively were excluded from analysis due to insufficient detail to ascertain incident type or wrong categorisation by NRLS.
- 120 (54%) of the remaining 222 reports had misclassification of harm severity.
- Only 47 (21%) incidents resulted in confirmed severe harm (n=20, 9%) or death (n=27, 12%).
- 55 (25%) reports had no clear stated outcomes to determine harm severity.
- Adverse events and wrong item dispensed were the top two incident types resulting in severe harm or death outcomes (Table 1).

Box 1. Edited extracts of incident reports (important points highlighted)

Example 1. Severe harm

*A prescription was received for prednisolone 5mg tablets take 6 each day. Correct labels were produced and split to 1 x 28 and 1 x 14, the treatment was for an emergency for COPD patient so was not taken until October. The patient was **admitted to hospital** around the 23rd October and the incident was reported to the pharmacy on the 24th October 2013. It appears that **gliclazide 80mg box was given with the label for 14 prednisolone 5mg tablets**. The patient was admitted to hospital in a **hypoglycaemic coma** and is seriously ill. The Hospital informed the pharmacy and provided photo evidence of the box of gliclazide with the label for 14 prednisolone attached and a complete strip of 14 gliclazide 80mg tablets and a strip of 14 Prednisolone 5mg tablets with 6 tablets missing. To date, the box of 28 tablets has not been found so it is impossible to determine if gliclazide or Prednisolone were dispensed. The error is being investigated by several parties. It appears to be due to **human error** on the part of the pharmacist possibly aggravated by **similar packaging** between ACTAVIS gliclazide and ACTAVIS Prednisolone tablet packaging both being purple and white in colour. It is possible that the two drugs arrived in the same order and an **error in putting the goods away** may have compounded the error.*

Example 2. Death

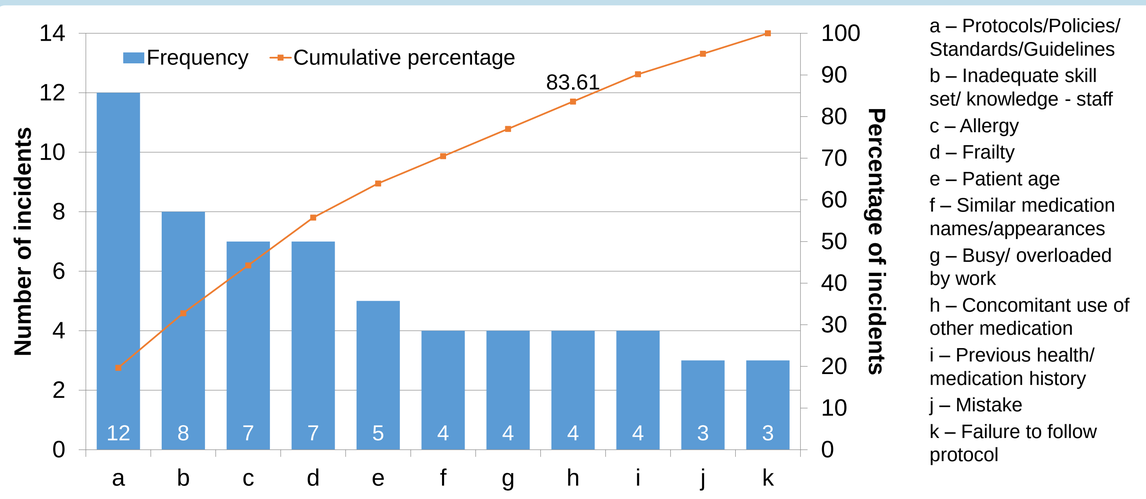
*Patient was prescribed amoxicillin. The clinical notes showed a record of **penicillin allergy** but amoxicillin had been **prescribed in the past**. It was therefore taken from **past acutes on the computer** and prescribed. Patient died later that day.*

Table 1. Most frequent incident types and their harm severity (n=47)

Primary incident types	Harm severity		Total
	Severe	Death	
Adverse Events	4	6	10
Wrong item dispensed	6	1	7
Wrong strength dispensed	3	0	3
Overdose dispensed	0	3	3
Medication prescribed for known allergic patient	0	3	3

- Problems with protocols/policies/standards/guidelines and inadequate skill set or knowledge by staff were the most commonly described contributory factors (Figure 2).
- Only 19 (10%) of the 186 categorised severe incidents were correctly classified as severe while 23 (64%) of the 36 death incidents were correctly classified.
- Some of the most frequent medicines involved in these incidents include opioid analgesics (n=8), warfarin (n=8) and antibiotics (n=8).

Figure 2. Most frequent contributory factors (n=47)



Discussion

Adverse events and wrong item being dispensed were the most common incident types involved in severe harm or death. Problems with protocols, policies, standards or guidelines being inadequate, inefficient, absent or not available were the highest contributory factors found to be involved in severe harm or death. A number of incidents had insufficient detail to accurately understand their nature. Coding of the free text allowed reclassification of the NRLS information to enhance data quality; however some records were unclassifiable making analysis conservative. The majority of incidents were incorrectly classified with the majority having an overestimation of severity. Using the reported harm severity to identify the initial sample may not have identified all incidents where death or severe harm actually occurred. Cousins[2] reported only 8.5% of medication incidents reported to NRLS were from primary care, even though the majority of medication use is here suggesting under-reporting which may impact on the generalisability of these results. Contributory factors a-h (Figure 2) were responsible for more than 80% of the incidents and interventions to improve medication safety should be focused on these areas to have maximum impact. We would further suggest that interventions to improve the quality of reporting be considered.

References

1. Carson-Stevens A, Hibbert P, Avery A et al., A cross-sectional mixed methods study protocol to generate learning from patient safety incidents reported from general practice. *BMJ Open*, 2015. **5**(12).
2. Cousins DH, Gerrett D, and Warner B, A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010). *Br J Clin Pharmacol*, 2012. **74**(4): p. 597-604 .

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