Medication without harm: developing optimal medication error reporting systems

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Medication errors (MEs) are amongst the most frequently occurring health care related incidents and have the potential to lead to life-threatening harm to patients. An incident reporting system is a traditional approach to improvement of patient safety and entails the retrieval of information from incident reports. This not only provides a better understanding of causes and contributing factors but also enables the collection of data on the severity of incidents, system deficiencies and the role of human factors in safety incidents. Medication error reporting systems are often developed as a part of larger incident reporting systems which deal with other types of incidents. Although a rise in the prevalence of medication errors has led to an increased demand for medication error reporting, little is known about characteristics and limitations of medication error reporting systems. The authors broach the subject of medication error reporting systems and propose a more robust and standardized approach.

**PERSPECTIVE**

**Medication Without Harm: Developing Optimal Medication Error Reporting Systems**

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**Abstract:** Medication errors are amongst the most frequently occurring health care related incidents and have the potential to lead to life-threatening harm to patients. An incident reporting system is a traditional approach to improvement of patient safety and entails the retrieval of information from incident reports. This not only provides a better understanding of causes and contributing factors but also enables the collection of data on the severity of incidents, system deficiencies and the role of human factors in safety incidents. Medication error reporting systems are often developed as a part of larger incident reporting systems which deal with other types of incidents. Although a rise in the prevalence of medication errors has led to an increased demand for medication error reporting, little is known about characteristics and limitations of medication error reporting systems. The authors broach the subject of medication error reporting systems and propose a more robust and standardized approach.

**Keywords:** Medication error, medication error reporting system, risk management, patient safety.

Medication errors (MEs) are amongst the most frequently occurring health care related incidents and are defined as an unintended failure in the drug treatment process that leads to or has the potential to cause harm to the patient [1]. In recognition of its significance, the WHO launched its 3rd global patient safety challenge in 2017—‘Medication without harm’ in an attempt to reduce avoidable medication harm by 50% over 5 years [2]. There is a wide variety of medication errors relating to issues with patient identification, drug dose, timing, route and allergy status. These can occur at any stage of the medicine intervention process such as during therapeutic decision making, prescribing, dispensing, administration and monitoring. Specific drug factors such as ‘look alike’, ‘sound alike’ and drug-drug interactions, are well recognized to increase the risk of a medication error [3, 4]. The inevitable changes that have occurred in the clinical environment over time due to a rapid increase in complex medical conditions, an aging population, polypharmacy and issues with medicines reconciliation, particularly during transitions of care [5], have also contributed to the occurrence of medication errors. Furthermore, whilst health information technology has played a substantial role in reducing medication errors, it is also suggested that it might introduce novel types of medication errors [6]. Table 1 summarizes key factors which might contribute to MEs.

**Table 1: Key factors contributing to MEs.**

<table>
<thead>
<tr>
<th>Health care professionals</th>
<th>Communication [7], stress [6], junior doctors [9]</th>
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</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Patient characteristics [10], informal carers [11], polypharmacy [12, 13], high risk group (aging population [14], pediatric [15, 16], allergy [17], palliative care [18], mental health [19], pregnancy [20], trauma [21], chemotherapy [22, 23])</td>
</tr>
<tr>
<td>Work environment</td>
<td>Shift work and workload [24], interruption [25], specialized departments (intensive care unit [26, 27], operation room [28, 29], emergency department [30])</td>
</tr>
<tr>
<td>Medicines</td>
<td>Label [31-33], look alike sound alike (LASA) medication name [3], high risk drugs [34-40]</td>
</tr>
<tr>
<td>Tasks</td>
<td>Verbal orders [41], handwriting [42], abbreviation [43]</td>
</tr>
<tr>
<td>Computerized information systems</td>
<td>Electronic medication management system [44, 45], smart pump technology [46]</td>
</tr>
<tr>
<td>Interface</td>
<td>Transition of care [47, 48]</td>
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In view of the obvious risk of medication errors to patient safety, there have been a number of initiatives aimed at mitigating this issue. In the UK, ‘Never Events’ are defined as patient safety incidents that are wholly preventable if guidance or safety recommendations are available at a national level [49]. ‘Never events’ are often related to medicines use but other events are classified into surgical, mental health or general and the list is reviewed regularly. The up-to-date medicines related ‘Never Events’ includes the overdose of insulin, mis-selection of intravenous potassium solution concentrations, overdose of methotrexate for non-
cancer treatment, mis-selection of high strength midazolam during conscious sedation and administration of medication by the wrong route [34]. These were selected on the basis of the potential to cause significant patient harm including death. Pharmacist-led information technology intervention (PINCER) is one of the successful examples which have shown the effectiveness of reducing a range of medication errors with computerized clinical records in UK General Practices [50]. Electronic medication administration records (EMARs) and bar-coded-medication administration (BCMA) have been implemented to reduce the risk of errors related to handwriting, omission and transcription and have also led to significant reductions in the number and types of medication administration errors [51, 52]. However, further studies have been suggested to evaluate human factors and technical issues which might adversely affect bar-code scanning techniques in achieving complete elimination of medication administration errors [53]. The inherent complexity of medication errors, the variation in organizational culture and situational context pose some unique challenges against generalizability and the flexibility of organizations to adapt to change [54, 55].

On the international scene, only few studies have compared medication errors between countries. Wahr et al examined intensive care unit medication errors reported to the United States’ MedMarx and the United Kingdom’s National Reporting and Learning System (NRLS) [56] and reported differences in the types of errors and medications observed. They concluded that differences in medication practices and/or in reporting cultures may account for these findings and this warranted further investigation. Cheng and colleagues deduced that the impact of alerts and newsletters on medication errors in Canada, USA and UK could also be relevant to the Netherlands [57]. They identified 90 issued items by these three countries and although 79 (87.8%) were found to be relevant to Dutch healthcare only 14 (16%) of the 90 items had been disseminated as an alert or newsletter. Bjerre et al explored overlap of subject and timing of medication safety letters issued in Canada, USA and UK where medical practice is otherwise comparable. Significant discrepancies were found in both the subject and timing of medication safety letters issued by health authorities in these three countries [58]. Similarities and differences in national reporting systems could provide learning opportunities not only for medication errors but also for medication error reporting systems.

An incident reporting (IR) system is a traditional approach to the improvement of patient safety. Retrieving information from incident reports provides not only a better understanding of causes and contributing factors but also enables the collection of data on the severity of incidents, system deficiencies and the role of human factors in safety incidents. However, IR systems have weaknesses such as underreporting, clinicians’ lack of engagement, insufficient institutional and financial support, a lack of clarity on actions for improvement and suboptimal use of health information technology [59]. Therefore, the effectiveness, limitations and recommendations for improvement of IR systems have remained important topics for consideration [60, 61].

Medication Error Reporting (MER) systems are often designed as a part of larger IR systems which deal with other types of incidents. In 2012, Holmstrom et al focused on MER and explored its characteristics nationally and locally in a cross-sectional study. The researchers found eight national/local MER systems, and reported difficulty in identifying national medication error experts. The conclusion was that promoting international networking of medication safety experts and organizations is essential for the sharing of information and learning from others [62]. The research group went on to publish factors at the national and local levels which might impact on the functionality of MER systems [63]. However, there is a dearth of evidence regarding the successful development and implementation of MER systems and it remains unclear what progress might have been made. In support of WHO’s campaign, the Department of Health & Social Care in the UK established a Short Life Working Group (SLWG) in 2017 aiming to improve medication safety [64]. Their recommendations included approaches such as electronic-prescribing and medicines administration [65], PINCER [50] and the involvement of patients and carers in the decision making process with the aim of developing more effective communication between patients and clinicians. Regarding MER, the recommendation is that professional regulators and leadership bodies are expected to encourage reporting and learning from medication errors but there is a lack of clarity on whether this is to be achieved via a unified process.

Recently, the inconsistencies in medication safety taxonomy and the lack of a standardized classification have been highlighted [66, 67]. Other issues are related to the quality of narrative reports and the difficulty of extracting, analyzing and learning from medication errors. The lack of an evaluation tool for narrative medication error reports is suggested to contribute the difficulty to integrate useful information [68]. Incident reporting is one of the main methods for medication error detection, but barriers to reporting remain a major concern and are associated with underreporting. Other methods include medication chart review, computerized monitoring, administrative databases, claims data, direct observation and patient monitoring, but no single method is optimal [69]. There is growing awareness of the limitations of current practice regarding the investigation of patient safety incidents [70] and medication error reporting is no exception.

In the UK, adverse drug reactions (ADRs) are monitored by the ‘Yellow Card Scheme’ which is a national voluntary reporting system collecting information on suspected ADRs from healthcare professionals and the general public. This is an established reporting system which can be adapted and built upon to formulate a medication error reporting system.
that is accessible to healthcare professionals and fit for purpose. The National Health Service (NHS) in England and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK formed a partnership to work together in response to the EU Directive on pharmacovigilance in 2014. This was in order to minimize risks from the use of medicines by increasing the number and quality of medication error reports, improving timeliness of reporting and better local and national communication. Such collaborations with healthcare regulators are vital to improving patient safety and may act as a template for other countries [71]. Improvements in education and training, better human factors and systems management and optimal use of information technology [70, 72, 73] have all been highlighted as key approaches to drug safety and should be integrated into current clinical practice [74]. As a result, deploying and scaling technology to be able to develop predictive algorithms and risk scores which might enhance medication safety is a priority research area. [75].

MER systems have the potential to play a more prominent and important role in medication safety, but little is known about characteristics and limitations which might shape its applicability in clinical practice. In addition, currently, there are no evidence-based guidelines to support their utility and effectiveness or highlight challenges which might be mitigated by a strategic approach to MERs (Table 2). It is about time that the essential role of MER is considered to drive drastic change with an emphasis on anonymity and non-punitive action. Furthermore, in response to the rapidly changing situation, appropriate data elements for robust MER systems might require updated taxonomy and streamlined information gathering techniques. Utilization of information technology in the form of artificial intelligence might lead to optimization reporting systems and provide an opportunity for effective information extraction. Universal sharing and learning require standardized classification, outcome measures, visibility and accessibility, particularly for healthcare professionals, and this is essential for better MER systems. The lack of an internationally acceptable MER system should prompt research which might elucidate key features and barriers that might affect the development of optimal MER systems.

As part of a research project in this subject area we hypothesize that: 1) MER systems are suboptimal; 2) There is no significant difference in MER systems between countries; 3) There are the barriers to the implementation of MER systems; 4) MER systems are often integrated with other patient safety systems and this might lead to lack of clarity in learning from reports; 5) Learning and quality improvement following medication errors is suboptimal. We are currently in the process of: 1) identifying how medication errors are reported internationally; 2) evaluating the differences between countries; 3) exploring/identifying the barriers to the development of optimal MER systems; 4) comparing comprehensive incident reporting systems with standalone MER systems; 5) attempting to elucidate how we can better learn from MER. Our ultimate goal is to identify gaps and barriers with a view to proposing the optimal approach to an effective MER system.

### Table 2: Medication error reporting systems in focus

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<th>Challenges facing MER systems</th>
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<tbody>
<tr>
<td>• Various definitions and classification</td>
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<td>• Issues of detection and true prevalence</td>
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<td>• Various MEs changing over the time</td>
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<tr>
<td>• Barriers to reporting/Underreporting</td>
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<tr>
<td>• No guidance on quality of MER/ Low reporting quality</td>
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<tr>
<td>• Lack of universal reporting form</td>
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<tr>
<td>• Poor evidence in MER effectiveness</td>
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<td>• Lack of sharing information locally/nationally</td>
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<tr>
<th>Strategic directions towards optimal MER systems</th>
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<tr>
<td>• Targeted approach to targeted events (Never events)</td>
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<td>• Effective utilization of technology</td>
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<tr>
<td>• Utilisation of big datasets facilitated by appropriate information technology</td>
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<tr>
<td>• Optimisation of reporting system and information extraction</td>
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<tr>
<td>• Development of an educational approach</td>
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<tr>
<td>• Information sharing and partnership</td>
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<tr>
<td>• Use of Medicines governance system redesign</td>
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<td>• Change of organisational culture to reflect MER</td>
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### LIST OF ABBREVIATIONS

- IR = Incident reporting
- MER = Medication error reporting
- PINCER = Pharmacist-led information technology intervention
- EMARs = Electronic medication administration records
- BCMA = Bar-coded-medication administration
- NRLS = National Reporting and Learning System
- SLWG = Short Life Working Group
- ADRs = Adverse drug reactions
- NHS = The National Health Service
- MHRA = the Medicines and Healthcare products Regulatory Agency

### CONFLICT OF INTEREST

The authors have no conflicts of interest relevant to this article to disclose.

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Drs. Shiima, Malik, and Okorie conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.
REFERENCES


17. Mortell, M., Should known allergy status be included as a medication administration 'right'? Br J Nurs 2018, 29 (20), 1292-1298.


42. Hartel, M. J.; Staub, L. P.; Roder, C.; Eggle, S., High incidence of medication documentation errors in a Swiss university hospital due to the handwritten prescription process. *BMC Health Services Research* 2011, 11, 199.


58. Bjerre, L. M.; Parlow, S.; de Launay, D., et al., Comparative, cross-sectional study of the format, content and timing of medication safety letters issued in Canada, the USA and the UK. *BMJ Open* 2018, 8 (10), e020150.


