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2015-08

Holmström , A-R , Laaksonen , R & Airaksinen , M 2015 , ' How to make medication error reporting systems work : Factors associated with their successful development and implementation ' , Health Policy , vol. 119 , no. 8 , pp. 1046-1054 . <https://doi.org/10.1016/j.healthpol.2015.03.002>

<http://hdl.handle.net/10138/157042>

<https://doi.org/10.1016/j.healthpol.2015.03.002>

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Please cite the original version.

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

How to make medication error reporting systems work – Factors associated with their successful development and implementation

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ARTICLE INFO

Article history:

Received 24 September 2014

Received in revised form 3 February 2015

Accepted 3 March 2015

Keywords:

Incident reporting

Medication error reporting

Patient safety

Medication safety

Systems approach

ABSTRACT

This study explored factors associated with successful development and implementation of medication error reporting (MER) systems in different healthcare contexts. A descriptive online questionnaire comprising of structured and open-ended questions was responded to by 16 medication safety experts in 16 countries. The present paper describes the rich and multidimensional qualitative data from the experts' narratives from open-ended questions. Several factors related to the national context of MER systems, i.e., the operational environment, were identified to impact successful development and implementation of these systems. The factors were: awareness of deficiencies in medication safety at local and national levels to justify the need for MER systems; gaining political will for the development and implementation actions together with international and governmental support; creating or reforming legislation and national regulations, guidelines and strategies to support MER; allocation of adequate human and financial resources; establishment of an organisation or centre to coordinate and lead MER; and extending systems approach and safety culture to all parts of the operational environment to facilitate openness on and learning from medication errors. In conclusion, operational environments of MER systems must be constructed to support functionality of these systems, and need to be improved in many countries.

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1. Introduction

Medication errors constitute a serious threat for health-care safety internationally [1]. They are defined as any preventable events that may cause or lead to inappropriate medication use or patient harm while the medication

is in the control of the health care professional, patient, or consumer [2]. Medication errors can occur during various stages of the medication use process, e.g. while prescribing, dispensing or administering a medicine [3]. It has been estimated that medication errors cause the death of 7000 patients annually in the United States alone [4]. Studies on medication errors have shown them common and costly; medication errors and other adverse drug events cost tens of billions of dollars for healthcare systems around the world each year [3].

The current understanding about learning from medication errors is based on the systems approach stating that errors are mainly consequences of systematic factors and

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organisational weaknesses [5]. To detect and learn from medication errors, medication error reporting (MER) systems have been recommended as tools to manage safety risks in medication use [6,7]. The primary goal of MER is to ensure long-term quality improvements in healthcare by understanding the systems factors contributing to medication errors, not plain counting of errors [7]. Thus, MER systems should support achievement of this goal.

Some countries have implemented local and/or national MER systems into their healthcare systems [8]. While MER practices may have varied between healthcare settings and countries, they have encountered similar difficulties, for example with healthcare professionals' lack of willingness to report errors [9,10]. Other central barriers to reporting have found to be healthcare professionals' lack of time for and training in reporting, and the lack of organisational leadership and support for reporting and learning from errors [8]. Therefore, the information and lessons learnt from countries with a current system are essential in maintaining existing systems, and in the development and implementation of new systems. While many MER systems are under development [11], this information is needed. As little previous research has been conducted on the development and implementation of MER systems in healthcare, our aim was to explore what makes a MER system work and what are the factors associated with the successful development and implementation of national and local MER systems in different healthcare contexts.

2. Materials and methods

2.1. Study design

The data was collected by consulting medication safety experts knowledgeable about MER systems in their own countries. The study produced both qualitative and quantitative data. In the present paper we concentrate on the rich and multidimensional qualitative data; the quantitative findings have been reported elsewhere [8]. However, some of the quantitative data was used to support the interpretation of the qualitative data. This information comprised of the existence of a MER system in an expert's country, type of system (local or national), and whether the system was used for reporting all patient safety incidents or only medication errors [8]. An ethical approval was obtained through the University of Bath (UK) ethical review process.

2.2. The data collection instrument and participants

A descriptive cross-sectional online questionnaire, comprising of open-ended and structured questions, was developed and administered to 32 medication safety experts in 26 countries in Spring 2007. Through the experts we sought for information on aspects that were regarded central in relation to current MER systems [6,7].

The systems approach on risk management served as the theoretical foundation of the questionnaire [5]. The recruitment process of the experts has been described elsewhere [8].

Through the qualitative data obtained from 20 open-ended questions for narratives, we aimed to gain

information on the national contexts where the MER systems operated in the experts' countries or would operate if developed and implemented (Fig. 1). We also acquired information on whether this national context, i.e., the operational environment, comprising of organisations (e.g. national authorities), systems (e.g. medical liability systems), and individuals participating in reporting (e.g., healthcare professionals) and governing reporting (e.g., policy makers) and using the information produced on medication errors, supported the functioning of MER from a systems approach. Consequently, all experts were asked about the legislation and regulations related to MER, and patient and medication safety in their countries (Fig. 1). Additionally, the roles of different authorities in MER, quality and safety management in healthcare, and patient and medication safety were investigated.

Also other aspects related to the development and implementation of MER systems and their maintenance in the experts' countries were investigated (Fig. 1). From the experts in countries without a MER system, we aimed to acquire an insight into how the operational environment should be constructed to support the development and implementation of a MER system in those countries.

2.3. Data processing and analysis

Qualitative content analysis was applied with an inductive approach [12,13]. Data was received in a Microsoft Excel-file, and was transferred to Microsoft Word-files for analysis. The data from all open ended questions was combined to obtain a comprehensive understanding about the issues under exploration. The thoughts or themes occurring in the experts' narrative responses were selected as the analysis unit [13]. The responses were read repeatedly, so that the occurring key elements and words started to emerge from the data and could be listed in the margin of the text to describe all aspects of the content. The most frequently occurring themes and words were further used as the codes for the main themes of the text. The codes (e.g., *Feedback for the healthcare staff involved in reporting*) were then applied systematically to the entire data. The outcome of the analysis was identification of the themes (e.g., *Learning from medication errors*; Table 1) and clusters of themes (e.g., *MER systems*) that described the construction of MER systems' operational environments in the experts' countries and the factors for successful development and implementation of MER systems. The analysis was performed by the first author (ARH), and the credibility of the coding was checked by the second author (RL) to ensure analytical rigour. In 2010, the data was reanalysed to confirm the accuracy of the coding. Consequently, some codes, themes and clusters were subjected to minor changes.

Based on the findings, a model to assist in the development and implementation of MER systems was developed and presented in the form of a diagram (Fig. 2). While the components of the diagram are directly based on the data, their order partially represents the views of the researchers to provide a concrete tool for countries willing to develop and implement a MER system, or to improve their existing system. The views of the researchers were based on

Fig. 1. Proposed factors for successful development and implementation of medication error reporting (MER) systems (based on qualitative analysis of responses from 16 medication safety experts). The upper part of the figure describes the open-ended questions asked from the experts.

the systems theory [5], existing evidence and recommendations on MER systems [6,7], and experiences in Finland [14,15].

3. Results

Overall, 16 experts (5 females, 10 males and 1 gender unknown) responded from a heterogeneous group of 16 countries in Africa (Ghana, Rwanda and Zambia), Australasia (Australia, Japan and India), Europe (Austria, Czech

Republic, Finland, Hungary, Kosovo, Latvia, Norway, Serbia and Sweden) and North-America (Canada) [8]. Figs. 1 and 2 describe the factors necessary for the development and implementation of a successful MER system. These factors were suggested by the experts and were identified to be related to the operational environment of MER systems. The following paragraphs describe these factors in more detail. Moreover, the operational environments of MER systems were identified as inadequate to support functional MER in the experts' countries.

Table 1

Examples of expert quotes about medication error reporting (MER) systems' operational environments and factors associated with successful development and implementation of MER systems.

Theme	No. ^a	Representative quotes
Establishing MER systems	1.	<i>This [development and implementation of a MER system] should also be done after the gaining of the political will and nothing can be best developed and implemented without the will of the governing authority. (Expert no. 18, developing country with a local MER system, setting not known)</i>
	2.	<i>Our country lacks in human, organisational and not less in financial resources. I think that with small pilot programme that could be planed, developed and implemented within 18–24 months, big progress could be achieved and sustainable reporting system will be established. Taking into consideration that our country is small with support of our colleagues from FIP and other health professional organisations, MER system in our country will be successful story. (Expert no. 9, developed country with no MER system)</i>
	3.	<i>The whole area [of legislation on adverse events] is not well promoted and there is fear of reporting especially since there are no clear systems for what the reports will be used for. Institutions are averse to reporting medication errors and errors are often dealt with quietly. (Expert no. 5, developing country with no MER system)</i>
Struggling with blame culture	4.	<i>The existing legislations require reporting. However, there is still need for more emphasis on the systems and processes behind human errors rather than blaming the individuals for errors. The government has recently started a government investigation to modernise the legislation in to this direction. (Expert no. 6, developed country with a national stand alone MER system)</i>
	5.	<i>Apart from the existing legislation and regulations there should also exist a regulation for legal protection against using the information [of reporting systems of adverse events and medication errors] for purposes other than learning. (Expert no. 24, developed country with a local MER system, setting not known)</i>
Learning from medication errors	6.	<i>Establishing of centre for MER will possibly improve the situation, but more important thing would be to educate healthcare professionals to report and to be aware that it is their professional and moral obligation. It would be useful to continuously have a contact with specific persons working in healthcare in order to deliver information about of necessity for MER. . . (Expert no. 13, developed country with no MER system)</i>
	7.	<i>We have the capability [for developing and implementing MER systems], but lack the motivation and training in this area. (Expert no. 7, developed country with no MER system)</i>

^a The number of the quote in the text.

3.1. Awareness of deficiencies in medication safety and gaining political will

General awareness of deficiencies in medication safety was reported to be lacking in four of the countries influencing the perceived necessity of MER systems. Consequently, creating such awareness among healthcare professionals, decision makers and the public was recommended as a preliminary mission to initiate the development and implementation process of a MER system (Fig. 2). Engaging policy makers was proposed as key to gaining political will for these actions (Table 1: Quote 1; Fig. 2).

Four experts suggested producing evidence on the incidence of medication errors in the healthcare system as a central means for creating the awareness among healthcare professionals, policy makers and patients of the need to improve medication safety. Similarly, a baseline survey on medication safety related deficiencies and needs of a specific country was proposed to give an understanding of, and guidance on, how to develop a MER system suitable for a particular country or healthcare system. Information campaigns for healthcare professionals and patients were suggested as a means to contribute to the general awareness of medication errors and an indication of how both professionals and patients could contribute to safe use of medicines.

3.2. International and governmental support, and resources

The lack of financial and human resources hampered the development and implementation of MER systems in three countries. Therefore, strong expectations for

governmental and international support and collaboration in these actions were expressed by the experts (Fig. 2). Despite the shortages, three experts expressed strong motivation and positive expectations towards the successful development and implementation of MER systems (Table 1: Quote 2). Small-scale local pilot MER systems were suggested as a way to explore the resources for developing a national system. Also the involvement of existing national organisations, such as pharmacovigilance centres and healthcare authorities, and their expertise was perceived as essential, especially when establishing national MER systems.

3.3. Establishment of an organisation or centre for MER

The need to establish a national organisation or centre for MER was emphasised (Fig. 2). Such an organisation was needed to create leadership and coordination in reporting, and for the utilisation of the reported data in order to promote medication safety and systems approach to error prevention. While in general the findings were found applicable to both national and local MER systems, establishment of a national organisation or centre for MER was thought especially crucial for national systems.

At the time of the study, the leadership and coordination in MER was reported to be lacking in the operational environments, although potential structures, such as national organisations for governing and regulating the quality of health services, existed in all of the experts' countries. These organisations were responsible for building and advancing a safer healthcare system and overseeing quality related activities in the healthcare sector. Regardless

Fig. 2. The steps towards development and implementation of medication error reporting (MER) systems and learning from errors (based on qualitative analysis of responses from 16 medication safety experts).

of the existence of these organisations, two of the experts described serious deficiencies in healthcare quality and safety in their countries, such as a lack of capability of their systems to provide best practice. The need for proper national strategies to enhance the quality and safety of healthcare were raised as prerequisites for improvement. In the majority of the countries these organisations were involved in promoting patient and medication safety, but they were not directly involved in MER.

National organisations dedicated to coordinating patient and medication safety promotion were also common in the experts' countries. The organisations developed

and executed national and international strategies on patient and medication safety, and sought for system-based solutions in their actions. In two countries these organisations were also responsible for increasing the public awareness of the safe use of medicines. In one country, several national organisations participated in patient and medication safety promotion, each focusing on their specific remit: one of the organisations was responsible for MER and providing lessons for all stakeholders. National and international collaboration of these organisations enabled extensive information sharing among stakeholders, support for reporting, and learning from medication

errors. Other experts wished for such an infrastructure to generate the required leadership in their own countries.

3.4. Safety culture and legislation on reporting

The existence of a safety culture for those involved in error reporting was reported to be essential in developing and implementing functional MER systems (Fig. 2), and was seen to be affected mainly by the legislation and regulations on adverse events. The criticism of mandatory reporting without any statutory protection for the healthcare professionals reporting was strong and was reported to discourage reporting in the experts' countries (Table 1: Quote 4). This reflected the situation in four countries, where legislation "encouraged reporting" by requiring healthcare professionals to report. Also the contested applications of the reported data reflected the absence of a systems approach to error prevention and the continuing struggle with a blame culture (Table 1: Quote 5).

A need to reform the current legislation on dealing with adverse events appeared to be essential for an operational environment that supports MER (Table 1: Quote 3); non-punitive measures and anonymity were perceived as good principles for legislation that would support reporting. Healthcare professionals' continuing fear of the consequences when unintentionally violating patient safety and its impact on the reporting process still represented one of the most central disincentives to the development and implementation of functional MER systems in the experts' countries (Fig. 2). Indeed, medication errors were considered as criminal acts in eight countries. Action in such situations varied from administrative warnings to legal proceedings or even withdrawal of licenses, depending on the severity of the error. In one developing country the lack of consistent legislation for handling violations had led to the inequality in the codes of conduct between healthcare professions, leaving them dependent on protection by their professional bodies.

3.5. Learning from medication errors

Learning from reported medication errors was perceived as the most valuable outcome of MER systems (Fig. 2). The experts emphasised exploring a system based on the mechanisms and causes of errors with less focus on solely quantitative approaches on counting errors. A comprehensive feedback system for transferring the created knowledge back to the different levels of the operational environment was reported to be essential when developing and implementing a MER system. Three experts described the development of educational materials and bulletins for healthcare professionals and stakeholders as a preferable means for providing feedback on reported data. Providing this information for the development of policy and practice guidelines in medication safety at national and local levels was thought to be crucial.

A climate fostering learning from medication errors was perceived to promote cultural changes and enable reporting (Fig. 2). However, in eight countries a lack of competence in and motivation for reporting was perceived to

hinder reporting (Table 1: Quote 6). As a solution, education on reporting was felt to have motivational value for healthcare professionals, and to promote their awareness of their moral obligation to report medication errors (Table 1: Quote 7).

4. Discussion

Altogether 16 national medication safety experts described the operational environments of MER systems in their countries and the factors associated with the successful development and implementation of these systems. Our findings give ample information on how the operational environment should support MER systems. To our knowledge, no previous research has explored these factors in such extent. Indeed, the lack of focus in operational environments may explain why many current MER systems are dysfunctional. In many of the experts' countries the environment did not support MER systems or appeared "not ready" for their development and implementation, even in countries where a MER system already existed. This represents a key finding as even the most technically sophisticated systems will not work if the context does not support their use. The greatest gaps between the current situation and the needs for improvement were in the legislation and leadership structures.

4.1. The culture of the operational environment is the corner stone

Our findings strengthen the position of safety culture as the key for a functional reporting system and are in line with the findings of previous studies [4,16]. The experts' descriptions indicated limited existence of the safety culture in the operational environments of MER systems in their countries. Traditionally, safety culture has been emphasised as an important component of organisations reporting medication errors [4,6,17]. However, implementing safety culture should not be limited to the organisations involved in reporting but should extend to other parts of the operational environment, such as medical liability systems or federal regulations guiding reporting practices. If these parts of the operational environment are not based on the systems approach and express safety culture, the practice in healthcare organisations they guide does not follow those principles. Thus, "the cultural maturity of the operational environment", i.e. the existence of safety culture, may represent a central success factor for the development and implementation of functional MER systems.

There also appeared to be a perceived lack of a systems approach as a theoretical foundation in organisational and national medication error prevention strategies and activities. To support safety culture and MER, the strategies and activities should express the systems approach as recommended for reporting organisations [6,7,14,18]. Moreover, the systems approach should become the theoretical foundation on which the structures of the operational environment are built, employing the same principles for the reporting system and its context.

4.2. *Raising awareness of deficiencies in medication safety*

The experts called for drawing attention to the need for safety improvements at local and national levels when developing MER systems. Although deficiencies in medication safety are well recognised by the international academic research [19], the gap between what has been scientifically shown and its implementation in practice still remains a challenge. Indeed, the experts' emphasis on the need for raising awareness of deficiencies in medication safety relates to the identified low overall perception of medication safety by healthcare professionals, policy makers and the public [20]. Awareness creation may require targeted actions, such as the suggested national and local surveys on the current state of medication safety to provide information on how best to develop a MER system. Carefully planned public information campaigns [21] aimed at patients and healthcare professionals may represent an additional strategy. Public campaigns may also provide the means to attract the attention of stakeholders in the government, policy makers, professional organisation leaders and regulatory bodies. For instance, in Finland, such a national programme operated in 2011–2014 to support healthcare organisations in the promotion of patient and medication safety [22].

4.3. *Need for political will to introduce MER systems*

The experts called for a stronger political will in the form of, e.g., policies or legislation on introducing viable MER systems. Despite the extensive evidence of the incidence of medication errors and the need for functional reporting schemes, incident reporting still needs to be addressed with more explicit plans of action in national health policies [23]. Indeed, national and local medication safety strategies should support establishing MER systems [7]. This might enable the creation of more politically recognised MER systems to advance health policy concerning medication safety and raise national or local commitment to safety improvements.

4.4. *National coordination and leadership to define responsibilities*

The need for an authority or organisation to coordinate reporting and provide a link between the actors in the operational environment appeared to be a prerequisite for the successful implementation of a MER system. This may be even more crucial for national systems: to fulfil their mission to produce and disseminate information on needed safety improvements, they require a nominated organisation operating between the reporting system and other stakeholders. While some sophisticated national coordination and leadership structures existed in some countries, in other countries such structures were lacking or poorly organised. Thus, our findings strengthen the recommendation for facilitating national information sharing [4,6].

Healthcare quality organisations seemed to exist in many countries; however, their support and contribution

to incident reporting was not what the experts called for. The existing authorities may be important in driving the overall quality of health services, but their current remit may be too wide to serve as recommended national focal points for MER. These experiences indicate a strong need to establish the current structures of these organisations, their areas of responsibility and their capacity to coordinate reporting.

4.5. *Legislation as a driving force of non-punitive reporting*

According to our findings, dysfunctional medical liability systems, also criticised by previous publications [4,17], continue to represent a challenge for the operational environments of MER systems. Overall, legislation did not seem to support the feasible use of MER systems in the experts' countries. Many experts reported that medication errors are considered criminal acts followed by disciplinary or legal action depending on the seriousness of the incident; little has changed [4,24]. A lack of, or diverse legislation on, patient safety violation situations may also represent a threat to reporting as it may lead to inequality between healthcare professionals. In countries where unified codes of conduct are lacking healthcare professionals may be dependent on informal codes of conduct. In those cases the seeds for safety culture may exist only for those groups of professionals who have the support of strong professional bodies. More research is needed to measure this problem and whether this is a particular problem for developing countries where healthcare regulation and medical liability systems may be even less developed. These issues remain also a challenge in the pioneering countries of MER systems, such as the United Kingdom, where pharmacists can be prosecuted for dispensing the wrong medicine [25]. To enable the implementation of MER systems and their use, a reform of legislation in all these regards remains a target for improving the operational environments.

4.6. *Need for adequate resources to introduce MER systems*

Many experts in countries without a MER system claimed that a lack of adequate resources prevented the development and implementation of a system. The requirements for establishing feasible systems include a mechanism for data collection and management, capacity to investigate the reported errors, technical infrastructure, classification system for errors, expertise for data analysis, and capacity to disseminate information and produce recommendations generated from data analyses [7]. However, if resources are scarce, alternative methods for identifying problem areas in medication safety may need to be considered. The suggested small-scale local pilot systems may be a cost-effective way to explore the resources and to strengthen local safety culture. It should be noted that implementing a reporting system without adequate resources for analysis of and feedback on reported data will not support learning.

4.7. Learning as the objective of the operational environment

Learning from the reported medication errors was seen as the foundation of MER systems. However, at the macro level the translation of lessons into action was perceived not only as the objective of a reporting system but the objective of the entire operational environment involving those drawing up policy and practice guidelines. The need for a comprehensive feedback system was strongly expressed, and has also been described in previous research and recommendations [6,7,9,26].

Healthcare professionals' lack of competence in medication safety and reporting was often reported. Indeed, only few errors are reported by the current MER systems, perhaps due to different views about medication errors, risks and reporting by different professionals and professional groups [27]. Healthcare staff may not be fully aware of what should be reported and how [28]. Some experts also felt that a lack of motivation hindered reporting, and education in medication safety has an essential role in tackling the described cultural and motivational challenges. Thus, interdisciplinary education may represent an important intervention in creating good practices in medication safety and reporting [29].

4.8. Strengths and limitations of the study

There were some difficulties in recruiting experts for this study; the limitations caused by the relatively low number of participating experts has been described elsewhere [8]. The chosen research method placed some restrictions on interpreting the data as probing questions could not be presented to explore further aspects raised by the experts [30]. However, the experts were able to provide detailed narrative information on the research questions. Similar issues were presented by experts from different countries, indicating that the issues related to MER systems may be universal to some extent. Thus, the findings can be valuable at the international level. However, there may be other factors affecting development and implementation of MER systems which our study did not explore.

The study was conducted some years ago, representing a potential limitation. However, we described problems in wide societal structures supporting healthcare quality and safety and provided solutions to these challenges: improvements in these structures tend to progress slowly. Therefore, we consider the presented information still valuable for healthcare planners, regulators and providers in high and low income countries planning to develop and implement a MER system, or willing to improve their current system.

5. Conclusions

Operational environments of MER systems must support functionality of these systems and need to be improved in many countries. Several factors at the national and local levels impact on the functionality of MER systems and should be considered in relation to their development and implementation. A lack of resources may inhibit

establishing MER systems in some countries, representing a target for international collaboration. The safety culture should be extended to all parts of the operational environment to facilitate openness on, and learning from, medication errors.

Conflict of interest statement

The authors declare that they have no conflicts of interest.

Acknowledgements

We wish to thank: Prof. Marjorie Weiss, University of Bath, UK, Dr. Tana Wuliji, University Research Co., LLC – Center for Human Services, US, Xuan Hao Chan, International Pharmaceutical Federation and the International Pharmaceutical Federation (FIP) for participating in the entire study process; Dr. Jane Sutton, University of Bath, United Kingdom, for reviewing the study proposal; the FIP Patient Safety Working Group and the World Health Organization World Alliance for Patient Safety for piloting the survey instrument, and the Finnish Cultural Foundation, the Finnish Pharmacists' Association, the Faculty of Pharmacy, the University of Helsinki, and the Finnish Pharmaceutical Industry Research Foundation for financial support. We also thank the Pharmacy Practice Group at the University of Bath, United Kingdom, and the Division of Social Pharmacy at the University of Helsinki, Finland, for their general support for the study. Finally, we are very grateful to all participants of the study for their valuable contributions and Mr. Richard Stevenson for reviewing the final article for its readability.

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