EXISTENCE AND CHARACTERISTICS OF NATIONAL AND LOCAL MEDICATION ERROR REPORTING SYSTEMS – A STUDY OF 16 COUNTRIES

Authors

Anna-Riia Holmström
Division of Social Pharmacy
Faculty of Pharmacy
University of Helsinki, Finland

Marja Airaksinen
Division of Social Pharmacy
Faculty of Pharmacy
University of Helsinki, Finland

Marjorie Weiss
Department of Pharmacy and Pharmacology
University of Bath, United Kingdom

Tana Wuliji
Pharmaceutical systems and human resources,
Washington DC, USA (at the present moment)
The International Pharmaceutical Federation
Hague, The Neatherlands (at the time of the study)

Xuan Hao Chan
The International Pharmaceutical Federation
Hague, The Neatherlands

Raisa Laaksonen
Division of Social Pharmacy
Faculty of Pharmacy
University of Helsinki, Finland (at the present moment)
Department of Pharmacy and Pharmacology

University of Bath, United Kingdom (at the time of the study)

Corresponding author

Anna-Riia Holmström

Address: Division of Social Pharmacy, Viikinkaari 9 C, P. Box 56, 00014 University of Helsinki Finland

E-mail: anna-riia.holmstrom@helsinki.fi

Tel.: +358 44 574 7018

Fax: +358 9 191 59884

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OBJECTIVES To explore existence and characteristics of national and local medication error reporting systems (MERSs), and to assess perceptions of national medication safety (MS) experts of a good and effective MERS and barriers to reporting.

DESIGN A descriptive cross-sectional on-line survey.

SUBJECTS AND SETTING 32 national MS experts identified from 88 member countries of the International Pharmaceutical Federation (FIP) and 3 additional countries.

OUTCOME MEASURES The existence and characteristics of national and local MERSs in the participating countries, perceptions of a good and effective MERS, and perceptions of barriers to reporting.

RESULTS 16 out of 32 identified national MS experts participated in the study, each from a different country (response rate 50%). A national (n=8) or local (n=5) MERS existed in 11 countries and did not exist in 5 countries. The most common feature of MERSs was confidentiality of reported information. The most often mentioned characteristics of a good and effective MERS were learning from errors, a non-punitive approach in reporting, and ease of use. Major barriers were blame culture, lack of time, lack of training and coordination of reporting.

CONCLUSIONS The blame culture, lack of time, training and coordination of reporting continue to be the major barriers to reporting. Learning from errors and a non-punitive approach to reporting were the most important features of a good and effective MERS. Difficulties to identify national MS experts indicate a need for establishing national and international networks for MS experts for information sharing.

INTRODUCTION

Medication errors (MEs) are the most common single cause of an error in healthcare (HC).[1] Despite this and the evidence supporting incident reporting as a leading initiative to improve medication safety (MS),[1-4] medication error reporting systems (MERSs) are still rare in HC systems.[3] However, some countries have established such systems at national or local levels to record MEs, to facilitate learning from factors related to MEs, and to take actions to prevent errors from happening.[4-9] Previous studies have often concentrated on exploring errors and error rates reported to MERSs in developed countries, mainly in United States and United Kingdom, instead of describing how these systems could be developed and implemented.[6,7,10,11] In addition, no previous studies have looked at the different characteristics of MERSs across countries. Nevertheless, such information could be helpful for countries without a system or those willing to improve their existing MERS. Moreover, it would be valuable to gather information from different types of countries as countries vary in terms of HC systems and socio-economic environments.[12,13]

This study was conducted to describe the state of MERSs in developed and developing countries and to explore characteristics of these systems. The specific objectives were to explore the existence and characteristics of national and local MERSs, and to identify perceived attributes of a good and effective MERS and barriers to reporting.

METHODS

Study design, subjects and setting

This was a descriptive cross-sectional on-line survey targeted to national MS experts knowledgeable about MERSs in their countries. To identify these experts, the network of the International Pharmaceutical Federation (FIP) was used. The FIP is a global umbrella organisation for pharmacy practice and pharmaceutical sciences which has patient safety (PS) as one of the strategic focus areas. [14,15] It collaborates closely with the World Health Organization (WHO).

In total, 120 FIP member organisations in 88 countries were contacted through the FIP Headquarters requesting support in reaching MS experts in their respective countries (Figure 1). The FIP also contacted 20 other organisations known through their networks inside and outside the member countries, giving 91 contacted countries. The countries were divided into developed and developing countries based on the United Nations' Human Development Index (HDI) which is a measure of a long

and healthy life, knowledge, and a standard of living.[12] Additional WHO statistics were collected on the quality and capacity of HC of these countries.[13] This information was used to test the representativeness of the participating countries of the wider sampling frame. An ethical approval was sought and obtained through the University of Bath ethical review process prior to study initiation.

Development, piloting and administration of the questionnaire

A self-completed on-line questionnaire was developed using the literature on recommended characteristics of a MERS, characteristics of the existing national and local MERSs, and challenges encountered in medication error reporting (MER) practices.[3,16-18] The questionnaire comprised a set of 29 structured questions divided into 3 sections. Section I explored the background information on respondent countries and individual respondents. Subsequently, the respondents were directed to Section II (countries with a national or local MERS), or to Section III (countries with no MERS).

The questionnaire was piloted through the WHO Alliance for Patient Safety and the FIP Working Group on Patient Safety for content and face validity. After the pilot and revisions, a link to the final questionnaire and the cover letter were emailed to the identified MS experts in spring 2007 and 2 reminders were sent to non-respondents at fortnightly intervals.

Data analysis

The data were received in Excel format and entered onto an SPSS 15.0 database for statistical analysis. The quality of data entries was ensured. Descriptive statistics using appropriate parametric and non-parametric tests were employed.[19,20]

RESULTS

Participating countries and respondents

Contact details of 32 MS experts working for national or other organisations involved in PS and MS in 26 countries (19 developed and 4 developing countries; unknown for 3) were received from the informants in spring 2007 (Figure 1). This implies a lack of international network in MS. Overall, 16 experts gave a usable response to the questionnaire, representing countries in Africa (n=3), Australasia (n=3), Europe (n=9) and North-America (n=1), giving a response rate of 50% (Table 1). The respondents represented a wide range of national and local organisations involved in improving PS and MS and quality of HC (Table 2). The countries of the respondents represented well the 91

sampling frame countries in terms of the variables selected to describe HC and the state of development (Table 3). The only statistically significant difference was found in the number of nurses per thousand inhabitants.

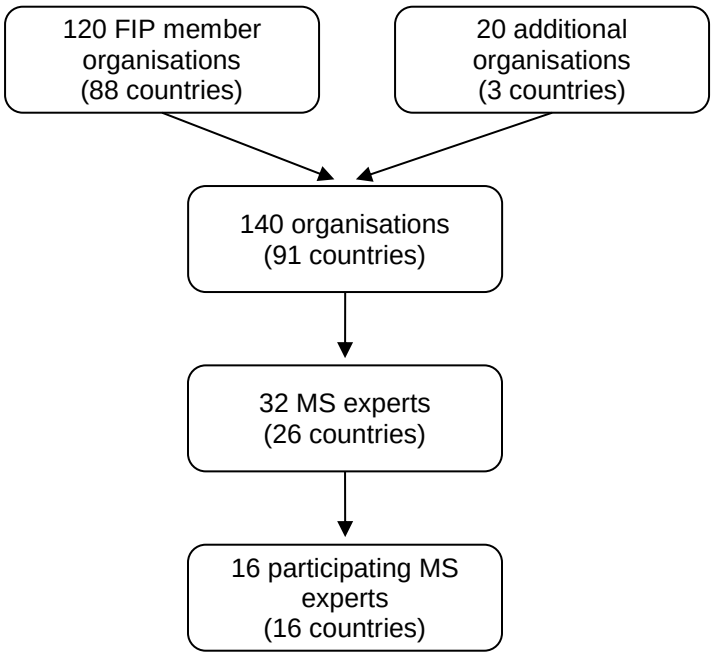

Figure 1 Recruitment process of the 16 participating medication safety (MS) experts who responded the questionnaire on medication error reporting systems in their countries. FIP = International Pharmaceutical Federation.

Table 1 Existence and type of medication error reporting systems (MERSs) in the countries of the participants (N=16).

MERS	Countries
National system	
Medication error reporting system	Canada*
	Japan*
	Sweden*
Integrated in an adverse event reporting system	Norway*
	Zambia **
Local system	
Within a community setting	Australia*
In community and hospital setting	Czech Republic*
A shared system between several hospitals	Finland*
Within a hospital setting	Hungary*
Setting not known	Austria*
	Rwanda **
No system	
	Ghana **
	India*
	Kosovo*
	Latvia*
	Serbia*

Footnote: *Developed country; **Developing country.

Table 2 Organisations of the respondents (N=16)

Organisations of the respondents	**n**
National Organisation	
Professional Body	4
Regulatory Body	4
Government and Professional Body	2
Independent Non-Profit Organisation for Patient Safety	1
National Corporation	1
Local Organisation	
Educational Institution	3
Hospital	1

Table 3 The characteristics of the participating countries (n=16) and the sampling frame countries (N=91), and the representativeness of the participating countries of the sampling frame countries.

Characteristic	Sampling frame countries (N=91)		Participating countries (N=16)		Non-participating countries (N=75)		P-value
	With statistics available (n)	Mean	With statistics available (n)	Mean	With statistics available (n)	Mean	
Population	75	16 760 920	13	11 959 154	62	17 767 742	NS §
Healthy life expectancy (years)							
Men	89	59.07	15	61.03	74	58,68	NS †
Women	89	62.06	15	63.00	74	61,87	NS †
Expenditure on health							
(USD) for healthcare/(USD) GNP*100% **	88	6.67	15	7.48	73	6,50	NS ‡
Tot. Expenditure on health/capita (USD)	88	948.18	15	1 527.93	73	829,05	NS §
Human resources/ 1000 inhabitants							
Physicians	89	1.76	14	2.17	75	1,68	NS §
Nurses	89	4.22	14	7.35	75	3,64	0.011 §
Pharmacists	80	0.40	13	0.55	67	0,36	NS §
Human Development Index (HDI)	85	0.754	14	0.804	67	0,744	NS †

§ non-parametric Mann-Whitney U test; † non-parametric Chi Square test; ‡ parametric t-test (exact, 2-tailed); *outliers and extreme values removed; ** Gross National Product; Statistics from World Health Organization and United Nations.[12,13]

Existence of MERSs and their characteristics

A MERS existed in 11 countries: 9 were in developed countries and 2 in developing countries (Table 1). 5 countries did not have a MERS. 8 respondents provided further information on 5 national and 3 local MERSs (Table 4). The most common characteristic of a MERS was confidentiality of reported information (6/8) (Table 4). The most common characteristics of national MERSs were: the MERS is provided and maintained by one national organisation (4/5); it is an integral part of a PS reporting system (4/5); it provides confidentiality of reported information (4/5); and it allows all healthcare professionals (HCPs) to report errors (4/5). On the other hand, all the local systems were reported to be easy to use (3/3), available electronically (3/3), allowed reporting of both potential and actual errors (3/3), and provided feedback on results of error analysis for those involved in reporting (3/3).

Table 4 Characteristics of the national and local medication error reporting systems (MERSs) in participating countries with a MERS and which provided further information (8/16). The characteristics are presented according to their frequency of appearance in national MERSs.

Characteristic	Type of MERS							
	National system					**Local system**		
	Canada	Japan	Norway	Sweden	Zambia	Australia	Czech Republic	Finland
The MERS provides confidentiality of reported information	X	X		X	X	X		X
The MERS is provided and maintained by one national organisation	X	X	X	X		X		
The MERS is an integral part of a patient safety reporting system		X	X	X	X			X
The MERS allows all healthcare professionals to report errors	X		X	X	X			X
The MERS provides feedback of results of error analysis for those involved in reporting	X	X		X		X	X	X
The MERS is paper based			X	X	X	X	X	
The MERS provides opportunity for error data analysis	X	X		X		X	X	
The MERS provides an opportunity for evaluating causes of errors (e.g. root cause analysis)	X	X		X		X	X	
Reporting of errors through the MERS is mandatory		X	X	X		X		
The MERS is available in electronic	X	X				X	X	X
The MERS includes reporting of both potential and actual errors	X		X			X	X	X
Reporting of errors through the MERS is voluntary	X				X		X	X
The MERS uses a non-punitive approach to reporting	X	X				X		X
The MERS provides a choice of reporting anonymously	X	X					X	X
The MERS produces recommendations and guidelines for improving medication safety	X			X		X	X	
The MERS is an independent reporting system dedicated for medication error reporting	X	X				X		
The MERS provides patients/consumers an opportunity to report errors	X				X			
The MERS is easy to use	X					X	X	X
The MERS is quick to use	X						X	X

Perceived characteristics of a good and effective MERS and barriers to reporting

The most often mentioned characteristics of a good and effective MERS were: the MERS should provide an opportunity for evaluating causes of errors (9/16); have a non-punitive approach to reporting (8/16); provide feedback of results of error analysis for those involved in reporting (8/16), and be easy to use (8/16) (Table 5).

Fear of consequences was the most commonly mentioned barrier to reporting (13/16) (Table 5). Other frequently mentioned barriers were culture of blame (8/16), a lack of training for reporting (8/16), a lack of time for reporting (8/16), and a lack of organisational leadership and support (7/16).

Table 5 Perceived characteristics of a good and effective medication error reporting system (MERS) and perceived barriers to reporting by the 16 respondents of the study. The respondents were asked to indicate five characteristics that they perceived as important in a good and effective MERS and five characteristics being the major barriers for reporting medication errors (structured questions with given alternatives were used).*

Characteristic of a good and effective MERS	**n**
The MERS provides an opportunity for evaluating causes of errors (e.g. root cause analysis)	9
The MERS uses a non-punitive approach to reporting	8
The MERS provides feedback of results of error analysis for those involved in reporting	8
The MERS is easy to use	8
The MERS provides opportunity for error data analysis	7
The MERS produces recommendations and guidelines for improving the medication safety	7
The MERS provides patients/consumers an opportunity to report errors	7
The MERS provides confidentiality of reported information	6
The MERS is provided and maintained by one national organisation	6
The MERS is an integral part of a patient safety reporting system	4
Reporting of errors through the MERS is voluntary	4
Reporting of errors through the MERS is mandatory	4
The MERS allows all healthcare professionals to report errors	3
The MERS is available in electronic format	2
The MERS is an independent reporting system dedicated for medication error reporting	1
The MERS provides a choice of reporting anonymously	1
The MERS includes reporting of both potential and actual errors	1
The MERS is quick to use	0
The MERS is paper based	0
Barriers to reporting medication errors	**n**
Fear of consequences	13
Culture of blame	8
Lack of training in medication error reporting for healthcare professionals	8
Lack of time for reporting	8
Lack of organisational leadership and support	7
Lack of legal protection for individual healthcare professionals who have made an error	6
Lack of relevant guidelines and policies on medication error reporting	6
Lack of understanding why reporting is needed	6
Concern that no beneficial action will follow	5
Non-anonymous reporting	5
Perceived to be bureaucratic	3
Lack of healthcare staff	3
Lack of financial resources	2

Footnote: * 1 country reported 9 characteristics instead of 5 and another 4 instead of 5.

DISCUSSION

Key findings

The study was stimulated by the current international need for developing MERSs and sharing experiences from existing systems.[1,3,21,22] Despite the current trends in shifting away from the blame culture in HC, the fear of consequences and the blame culture were still seen as the major barriers to reporting MEs. However, the non-punitive approach to MER was perceived as an important characteristic of a good and effective MERS. In practice the situation may still be different as only half of the countries reported non-punitiveness as a characteristic of their existing MERS, which may or may not be promoted by national legislation. Other barriers were a lack of training in MER for HCPs, a lack of time for reporting and a lack of organisational leadership and support. These findings support the current understanding that successful implementation of a MERS should focus on changing the blame culture and promoting learning from errors among practitioners and other stakeholders involved in MER.[17,23-25] To overcome these barriers to MER, well-coordinated, long-term collaboration between authorities, HCPs and educational organisations may be required, as well as potential changes in legislation.

The most common characteristics of MERSs were confidentiality of reported information and feedback of results of error analysis for those involved in reporting. These characteristics indicate that the majority of these national and local MERSs have been designed to include activities which provide opportunities for learning from errors and affecting the blame culture. However, confidentiality of the system does not exclude the chance of a HCP being punished for committing an error.

Interestingly, the most common characteristics of the national and local MERSs differed. It seems that the focus in national MERSs may be more in feasible nationwide reporting and learning, whereas local MERSs seem to be more focused on the feasibility of the reporting from the perspective of those reporting. To enable national MER, the system might need to be provided and maintained by one national organisation and to be an integral part of a PS reporting system enabling all HCPs to report errors. However, for feasible reporting, the characteristics of both national and local MERSs may need to be included in the MERS.

The findings were in line with the previous studies promoting learning from errors:[1,26,27] the survey showed that learning from errors was strongly emphasised as the most frequently reported characteristics of a good and effective MERS. This characteristic was also reported to be present in

most of the existing systems indicating progress in seeking systems based strategies to prevent MEs.[28] Consequently, the lessons for countries developing MERSs would be that learning should follow reporting: it was perceived that a MERS should provide an opportunity for error data analysis and evaluating the causes of errors as well as providing feedback of error analysis for those involved in reporting. The MERS should also produce recommendations and guidelines for improving MS at national and local levels. These activities might also contribute to understanding why reporting is needed and to ameliorate concerns of a lack of follow up after reporting, both of which were indicated as barriers to reporting. There were also other relationships between characteristics of a good and effective MERS and reported barriers. If training on reporting was implemented it would aid removing barriers to reporting which are due to insufficient training. If the MERS was easy to use, it might reduce barriers related to a lack of time for reporting.

Access to MS experts knowledgeable about MERSs in their countries proved to be the most challenging and time consuming part of the study. Despite the wide FIP networks and the help of the national professional pharmaceutical organisations, under one fifth of the contacted countries provided this information. This may be due to a lack of knowledge on MS and experts among the contacted organisations, indicating that PS and MS might be not nationally coordinated in many countries as recommended.[3] The findings also suggest that the international network for MS experts does not exist currently. When creating approaches to reduce MEs, such a network would be essential as it facilitates effective experience sharing on practices improving quality and safety of HC systems. As MERSs and reporting practices are under constant development,[29] there is a need for further research to explore the progress of these activities.

Limitations

The low number of respondent countries limits generalisability of the survey findings.[19] The response rate may have been influenced by the low number of countries which actually have a MERS. This, however, increases the need of disseminating information on the existing systems. Providing the questionnaire only in English may have contributed to the low response rate, as well as previously discussed challenges in accessing national MS experts. Furthermore, the recruitment of potential respondents was dependent on the informants in the national pharmaceutical organisations contacted by the FIP. Despite the low number of respondents, those who responded were able to provide detailed information on the MERS in their country. Additionally, the pioneering countries in MERSs such as United States and United Kingdom were missing from the data.

Conclusions

The blame culture, a lack of time, training and coordination of reporting continue to be the major barriers to reporting MEs and need to be targeted by continuous actions. In a good and effective MERS learning from MEs is the most important feature together with a non-punitive approach to reporting. The study indicates that national and local MERS may have different functions and characteristics that need to be taken into account when developing these systems. Further research is needed to learn more about these characteristics and to explore how MERSs and MER practices have developed and what have been the success factors, enabling factors and best practices for reporting. There is also a strong need for establishing international network for MS experts for information sharing.

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COMPETING INTRESTS

The authors declare that they have no competing interest relevant to the content of this manuscript.

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