

**EXECUTIVE SUMMARY OF THE FINDINGS**

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## 1. Introduction

Medication error reporting systems (MERSs) are currently rare in healthcare systems (Council of Europe 2007). However, some countries have established such systems at local and/or national levels in order to learn from factors related to medication errors, and to take actions to prevent errors from happening. As many of the current systems are in the first stages of the development process, a study was conducted to describe the state of medication error reporting systems in different countries and to explore the characteristics of these systems to offer advice on the development and implementation of these systems (Terzibanjan 2007). The aim of this document is to describe the key findings of the study and lessons learnt from establishing medication error reporting systems. This is to help countries to get started with development and implementation of medication error reporting systems and to learn from experiences on medication error reporting systems.

## 2. Methods

To explore national and local medication error reporting systems used in different countries, a self-completed on-line questionnaire using structured and open-ended questions was developed. An enquiry regarding identifying medication safety experts was sent to the 120 member organisations of the International Pharmaceutical Federation (FIP) and 20 other sources. The contact details of 32 medication safety experts were received in spring 2007, indicating a lack of an international network for medication safety experts.

## 3. Participating medication safety experts

Sixteen responses were received from different countries in the African (n=3), Australasian (n=3), European (n=9) and North-American (n=1) regions, yielding a response rate of 50% (Table 1). While eleven countries were classified as developed and three developing (Ghana, Rwanda and Zambia) according to the Human Development Index (HDI), the status of two countries (Kosovo and Serbia) was not known (United Nations 2006). Eleven developed or developing countries reported to have a medication error reporting system (Table 1; Appendix 1). The national systems, either stand-alone systems or integrated into adverse event reporting systems, were located in four developed countries in

Europe, North-America and Asia, and in one developing country in Africa. The local systems were located in hospital and other healthcare settings in five developed countries in Europe and Australasia, and in one developing country in Africa. As two of the three developing countries reported to have a medication error reporting system, there were no differences between developed and developing countries in the existence of medication error reporting systems.

Legislation on adverse events, comprising medication errors and adverse drug reactions, required mandatory reporting of adverse events in five out of 16 countries (Australia, Czech Republic, Japan, Norway and Sweden). However, in two countries the mandatory reporting related only to fatal or severe adverse events (Japan) and/or 'near misses' (Norway). In two countries (Canada and Zambia), the legislation on adverse events allowed voluntary reporting. Experts in two countries perceived that statutory mandatory reporting would not encourage healthcare professionals to report medication errors as they would be afraid of possible consequences, such as losing practising rights. In one country with no medication error reporting system, only legislation on reporting other adverse events existed (Kosovo UNMIK).

#### **4. Perceived characteristics of a good and effective medication error reporting system**

The respondents were asked to select the five most important characteristics of a good and effective medication error reporting system (U 2001; Council of Europe 2007). Many perceived that reported medication errors should be used to find the root causes of the errors (9/16). Almost as many (8/16) perceived that to learn from errors, the healthcare professionals involved in reporting should be given feedback of the results of the error analysis. The use of a non-punitive approach to reporting (8/16) was recommended to encourage healthcare professionals to report errors (8/16). It was also thought that reporting errors should be made as easy as possible to make sure that errors would not go unreported (8/16).

#### **5. Perceived barriers to reporting medication errors**

The respondents were also asked to select the five most important perceived barriers to reporting medication errors. The most common barriers to reporting medication errors were fear of consequences (13/16); a lack of time for reporting medication errors (8/16); a lack of training in medication error reporting for healthcare professionals (8/16); a culture of blame within healthcare (8/16); and a need for organisational leadership and support (7/16). Indeed a non-punitive approach to medication error reporting was perceived as an important feature of a medication error reporting system, but the above findings indicate that it may not be common practice. To overcome these barriers to medication error reporting and to implement the characteristics of a good and effective system in the current and prospective medication error reporting systems, collaboration between authorities and healthcare professionals and potential changes in legislation were perceived to be required.

## 6. Features of the existing medication error reporting systems

While eleven countries had a national or local medication error reporting system, only eight countries provided further information on their system (Table 1; Appendix 1). A medication error reporting system seemed to be likely to exist in the countries that had a national authority for patient safety (7/11) (Austria, Canada, Hungary, Japan, Norway, Sweden and Zambia) or for medication safety (7/11) (Australia, Austria, Canada, Japan, Norway, Sweden and Zambia). These findings may emphasise the important role of national authorities in developing, implementing and maintaining medication error reporting systems (Council of Europe 2007). However, in six countries (Australia, Austria, Czech Republic, Finland, Hungary and Rwanda) a local medication error reporting system existed despite a lack of a separate authority for medication error reporting. The findings indicated that an authority for medication error reporting might be needed to take the lead of the reporting process when developing a national medication error reporting system (U 2002; Council of Europe 2007).

**Table 1.** Existence, type and number of medication error reporting systems in the participating countries (N=16). Countries which provided further information about their existing medication error reporting systems are in bold.

<i>Medication error reporting system</i>	<i>Countries</i>
<b>National system</b>	
Medication error reporting system	<b>Canada</b> <b>Japan</b> <b>Sweden</b>
Integrated to adverse event reporting system	<b>Norway</b> <b>Zambia</b>
<b>Local system</b>	
In hospital or healthcare settings	
Within hospital setting	Hungary
Within community setting	<b>Australia</b>
A shared system with several hospitals	<b>Finland</b>
In community and hospital pharmacy	<b>Czech Republic</b>
Setting not known	Rwanda Austria
<b>No system</b>	
	Ghana India Kosovo Latvia Serbia
<b>Total</b>	<b>16</b>

Six medication error reporting systems safeguarded confidentiality of reported information and four systems allowed anonymous reporting of errors (Appendix 1). However, personal details of the person who made an error were required to be reported in three systems. This may discourage the healthcare professionals to report errors, but may be necessary in rare cases when harming a patient is intentional.

One local and four national medication error reporting systems were a part of a wider patient safety reporting system including reporting of different types of patient safety related incidents. This may indicate that the data on patient safety related harms produced by these systems may not be focused on medication errors alone. Consequently, this may lead to lower number of reported medication errors, while reporting of other adverse events may be emphasised. However, in practice, reporting all kind of adverse events through one system might be more convenient for practitioners to use.

Three national and two local systems used the collected data to investigate the causes of errors by using, for example, root cause analysis (Appendix 1). These systems were not used only to count the number of medication errors, but also provided means to prevent errors from re-occurring in the healthcare (Council of Europe 2007). In five countries all healthcare professionals were able to report medication errors through the system, which may increase the likelihood of different types of errors in the medication sequence to be reported. Indeed, prescribing, transcribing, dispensing and errors related to poor communication between a patient and a healthcare professional could be reported through all eight systems. However, it was not possible to report administration errors through one local medication error reporting system, indicating discrepancies between countries and potential underreporting of errors. Medication errors with fatal or severe outcomes, for example organ damage, were perceived the most likely errors to be reported. This may indicate that healthcare professionals may need to be convinced about the importance of reporting near misses to prevent these potential errors from becoming actual errors (Lawton and Parker 2002). The possibility to report both actual and potential errors, which was offered by five of the eight countries which had a medication error reporting system, may enable these countries to establish or improve a system approach to error prevention.

Pharmacists and doctors were perceived to report medication errors less often than nurses. This may indicate that nurses were more willing to report errors, or that the nursing staff were more likely to witness the occurrence of medication errors: most of the medication errors have been reported to be prescribing and administration errors (Bates et al. 1995; Lawton and Parker 2002). Patients were perceived to occasionally report medication errors, but were not allowed to report through six systems, which may lead to not detecting medication errors occurring outside the healthcare facilities, for example medication errors related to concurrent use of prescription medicines and over-the-counter medicines.

## **7. Strategies to develop and implement a medication error reporting system**

According to the responses to open-ended questions, the need for leadership of medication error reporting at national and local levels was perceived to be essential to ensure functional reporting. Other strategies for developing and implementing a medication error reporting system included the use of experiences from existing medication error reporting systems and pilot programmes for medication error reporting. This was suggested by the respondents to map the readiness and resources of countries without a system to establish reporting systems. To have a practical application and purpose for data reported through the medication error reporting system was thought important for the maintenance of an

existing reporting system. Indeed, many existing reporting systems used the data to learn from the errors and to train healthcare professionals to ensure the safety of healthcare (Council of Europe 2007).

### **8. Countries with no medication error reporting system**

Three of the five countries (Ghana, India and Serbia) where no national or local community medication error reporting system existed had taken actions to develop systems. Two of the countries (India and Serbia) were investigating medication safety issues within community settings. This led to actions to develop a medication error reporting system between several hospitals in India. Additionally, there were plans in Ghana to develop a medication error reporting system as part of an adverse drug reaction reporting system in a pharmacovigilance centre.

### **9. Conclusions**

This study described the extent and characteristics of existing medication error reporting systems mainly in FIP member organisation countries. At the national level medication error reporting systems were stand-alone systems or integrated with adverse event reporting systems. The local medication error reporting systems were based on hospital and/or community healthcare settings. However, the findings of the study may be considered to give an approximate idea of the situation in different countries as the limitations of the study do not allow generalisation of the results on the existence of medication error reporting systems to the sample frame countries. A set of recommendations for development and implementation process of medication error reporting system has been developed based on the study findings (Terzibanjan 2007).

The readiness of countries to develop and implement medication error reporting systems was also explored. It was found that there existed some plans and actions to develop and implement a medication error reporting system in these countries. The findings of this study suggested that a good and effective medication error reporting system should provide an opportunity for evaluating the causes of errors; use a non-punitive approach to medication error reporting; and provide feedback of results of medication error analysis for learning and education purposes for the healthcare professionals. However, more detailed future studies on what characteristics constitute an effective medication error reporting system are needed. Additionally, the stages of the development and implementation process of a medication error reporting system might be studied further.

### **References**

Council of Europe. Expert Group on Safe Medication Practices (2007) Creation of a better medication safety culture in Europe. Building up safe medication practices. Report.

Bates, D.W., Cullen, D.J, Laird, N., Petersen, L.A., Small, S.D., Servi, D., Laffel, G., Sweizer, B.J., Shea, B.F., Hallisey, R., Vliet, M.V., Nemeskal, R., Leape, L.L. (1995) Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *Journal of American Medical Association* 274:29-34

Lawton, R., Parker, D. (2002) Barriers to incident reporting in healthcare system. *Quality and Safety in Health Care* 11:15-18

Terzibanjan, A (2007) *Medication error reporting systems- Lessons learnt*, MSc(Pharm) thesis, University of Helsinki, Finland

U, D. (2001) Medication error reporting systems: Problems and solutions. *New Medicine* 1:61-65

United Nations (2006) Human Development Report 2006. *Beyond scarcity: Power, parity and the global water crisis*. Report

APPENDIX 1

Characteristics of the national and local medication error reporting systems in participating countries with a system.

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