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Original Article

ExpIR-RO: A Collaborative International Project for Experimenting Voluntary Incident Reporting In the Public Healthcare Sector in Romania

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Abstract

Background: Patient safety within healthcare systems is a central aspect of health policy in most developed countries. From April 2007 to May 2009, the pilot project ExpIR-RO tested a voluntary incident reporting system in a public hospital in Bucharest Romania, in collaboration with two Italian hospitals (in Genoa and Milan).

Methods: Data were collected anonymously through a form based on the Australian Incident Monitoring System. After appropriate training in reporting adverse events (AEs), staff in the participating Departments voluntarily completed the form. The study lasted 12 months in the Bucharest and Genoa hospitals and 3 months in the Milan hospital. Frequency distributions of replies and AE rates per 1,000 hospitalization days per month were assessed.

Results: Overall, 185 AEs were reported (58 in Bucharest, 75 in Genoa and 52 in Milan). The corresponding rates (per 1,000 hospitalization days per month) were 1 in Bucharest, 3 in Genoa and 15 in Milan. Most AEs were related to diagnostic (28%) and surgical (14%) procedures and patient falls (12%) in Bucharest; patient falls (32%), nursing care (20%) and diagnostic procedures (19%) in Genoa; and nursing care (25%), drug prescription/administration (21%) and diagnostic procedures (17%) in Milan. Seventy-three per cent of respondents in Bucharest informed the patient of the AE, versus 64% in Genoa and 43% in Milan. Conversely, 75% of respondents in Genoa entered AEs in medical records versus 53% in Bucharest and 36% in Milan.

Conclusion: ExpIR-RO experience suggests that incident reporting could be introduced on a larger scale in Romania.

Keywords: *Clinical risk, Adverse event reporting, Learning from incidents, Safety culture, Romanian-Italian collaboration*

Introduction

Over the last decade patient safety in healthcare organizations has become central in health policy in most developed countries. In Italy, after regional initiatives in Emilia Romagna, Tuscany and Lombardy, the importance of patient safety was acknowledged nationally through the creation of a Technical Commission for Clinical Risk Management within the Italian Health Ministry (2003) and the development of a National Reference System for Patient Safety (2006). Consequently, all hospitals in the Italian National Health System were required to undertake risk management and implement modern methods for identifying and analyzing clinical risk (1).

In Romania, incidents within the healthcare system have been raising serious concerns among professionals, patients and the mass media. As a

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new member of the European Union (since 2007), the country is required to meet European standards of quality in healthcare (2-4). And in its 2008-2010 strategy document, the Romanian Health Ministry affirmed its commitment to "implement standardized actions for patient safety" (5). However this is a major challenge because in order to prevent incidents it is first necessary to detect and monitor those that occur. In Romania there is very little experience of the modern methods of clinical risk identification and analysis used in the other European countries (3, 4, 6)

Voluntary Incident Reporting (IR) employs a form on which healthcare professionals reported detailed information about errors, injuries, non-harmful errors, equipment malfunctions, process failures or other hazards they encounter in their work. The aim is to identify unsafe conditions and learn from the experience to prevent the occurrence of similar events in the future. It should be stressed that reporting in itself does not improve safety. It is the response to reports that leads to change (7). Most voluntary IR systems are system-wide or regional, but in recent years several countries (e.g. Australia, England and Wales) have implemented voluntary national systems for reporting Adverse Events (AEs), in order to facilitate large-scale data analysis and learning (7, 8).

Between April 2007 and May 2009 the international pilot project ExpIR-RO (Experimentation of voluntary Incident Reporting in Romania) was implemented in a public hospital in Bucharest, in collaboration with two Italian hospitals. The aims were: (a) to develop the infrastructure necessary for the introduction of an IR system in the Bucharest hospital, and delineate the risk profile of the participating departments; (b) to identify corrective actions to reduce or eliminate risks; (c) to develop a safety culture favorable to the voluntary disclosure of AEs by staff so that the entire organization can learn from these events; (d) to share the knowledge gained with other professionals through post-graduate training programs across Romania; (e) to replicate the experience in other Romanian hospitals; (f) to learn from the experience of the two Italian hospitals involved in the project.

This paper presents the results of ExpIR-RO: the first testing of voluntary IR in a public hospital in Romania. The addition of Italian experience is important because, although voluntary IR is fairly well established in Italy, and some papers are available in Italian (9-11), little has been published in the international literature (12-14).

Materials and Methods

Partners and roles

Five departments of the University & Emergency Hospital Bucharest (Bucharest is the capital of Romania, located in the South-East of the country) with over 1,000 beds participated in the pilot project. The departments were Anesthesia and Intensive Care, General Surgery, Cardiology, Orthopedics, and Radiology. Two Italian hospitals (one in Genoa and one in Milan) provided expertise for implementing the project in Romania. The Genoa hospital is small (100-bed) and privately-owned. All its departments participated (General Surgery including Anesthesia and Operating Room, Internal Medicine, Obstetrics and Gynecology, Neonatology, Radiology, Laboratory, Medical Management and Administrative Departments). The Milan hospital is a cancer hospital specialized in research as well as treatment; it has about 400 beds. Four of its departments were involved (Intensive Care, Gastrointestinal-Pancreatic-Liver Surgery, Thoracic Surgery, and Hematology). The Department of Public Health and Healthcare Management of "Carol Davila" University of Medicine and Pharmacy, Bucharest, assisted the project coordinator (Romanian physician doing PhD in Italy) with coordination in Romania and organized post-graduate pilot courses on clinical risk management, to disseminate the knowledge and experience gained through ExpIR-RO.

Data collection and analysis

One doctor and one nurse per department were initially trained in voluntary IR and data collection by the project coordinator. This initial nucleus subsequently trained their colleagues so that within a month all the staff had received the necessary training for IR.

Data on AEs were collected on a paper IR form translated from one provided by the Italian partners which had in turn been adapted from one used by the Australian Incident Monitoring System (9, 15). After translation and adaptation of the form from Italian to Romanian it was tested for a month to ascertain adequacy for the specific conditions of the Bucharest hospital. After positive feedback the form was adopted definitively. The form was compiled anonymously. Hospital management and the project team guaranteed complete confidentiality and provided assurances that no disciplinary action would be taken against staff who reported AEs. Blank forms were available for all staff on the nursing desk. Completed forms were deposited in a box freely accessible to all staff and were collected by two project team members (resident physicians) who entered the data into a computer.

For study purposes, completed IR forms were collected at the Bucharest hospital (five participating departments) over two six-month periods (Oct 2007 to Mar 2008; June 2008 to Nov 2009). Data provided retrospectively by the Genoa hospital referred to the 12 mo of 2005 for the entire hospital. Retrospective data from the Milan hospital for the four participating-departments were for the 3 mo from March to May 2006.

Descriptive analysis involved determination of frequency distributions of answers to items on the IR forms. Rates of AEs per 1,000 hospitalization days per month were calculated according to the formula:

$$[No\ AEs_{month} / (No\ pat_1 * ALOS_1 + \ldots.\ No\ pat_n * ALOS_n)] * 1{,}000$$

where $No\ AEs_{month}$ is the monthly number of adverse events, ***No pat*** is the monthly number of discharged patients from each department, ***ALOS*** is the average length of stay in each department and ***n*** indicates the number of departments. The rate only applies to the pool of departments with beds (i.e. >0 beds in Table 1). The data were analyzed with Microsoft Excel 2003.

Definitions

An AE is an injury occurring during medical management and is distinct from disease complication. Medical management refers to all aspects of care including diagnosis and treatment, failure to diagnose or treat, and the facilities and equipment used to provide care. A potential AE (near-miss) is a serious error or mishap having the potential to cause an AE but does not do so because by chance or because steps taken in time to prevent injury (7).

The severity of reported AEs was assessed on a 1 to 8 scale. Levels 1 to 2 correspond to potential AEs; levels 3 to 8 correspond to actual AEs of increasing severity.

Results

Table 1 shows the main activity indicators in the departments participating in the study.

Table 2 tabulates the main information collected on the IR form in each hospital. There were 58 reported AEs in Bucharest (41 in departments with beds) over 12 mo; 75 in Genoa (56 in departments with beds) over 12 mo and 52 in Milan (all in departments with beds) over 3 mo. Thus, the number of AEs per 1,000 hospitalization days per month was 1 in Bucharest, 3 in Genoa and 15 in Milan.

Most AEs (83%) were reported by doctors in Bucharest compared with 55% and 50% in Genoa and Milan respectively. AEs were mainly diagnostic procedure-related (28%), surgery-related (14%) and patient falls (12%) in Bucharest; patient falls (32%), nursing care-related (20%) and diagnostic procedure-related (19%) in Genoa; and nursing care-related (25%), drug prescription/administration-related (21%) and diagnostic procedure-related (17%) in Milan.

System-related factors were in first place (Bucharest: 46%; Genoa and Milan: 51%) as contributors to reported AEs, followed by staff- and patient-related factors. The commonest severity level attributed to AEs by respondents was 3 in Bucharest (40%) and Genoa (31%). The commonest level attributed by Milan respondents to AEs was 1 (31%), however the Evaluation Commission (which re-assessed AE severity for the purpose of taking corrective action) assigned the most common AE severity for Milan as 2. Seventy-three percent (of 51 respondents) in Bucharest informed

the patient of the AE versus 64% (of 59 respondents) in Genoa and 43% (of 46 respondents) in Milan. By contrast, 75% (of 60 respondents) in Genoa entered AEs in patient records versus 53% (of 53 respondents) in Bucharest and 36% (of 44 respondents) in Milan (Figure 1).

Figure 2 shows the corrective actions proposed by Romanian respondents to prevent similar AEs in the future. The most important- which became priorities for the Bucharest hospital management- were: improvement in personnel training, review or modification of protocols/procedures, improvement in communication with patients and between services and assurance of better availability of materials and devices.

Forty-two Bucharest respondents expressed opinions about the risk of similar AEs occurring in the future if corrective measures were not taken: 52% of these thought the risk was high (≥1 AE per year with moderate to serious consequences) and 38% thought it was moderate (≥1 AE per year with minor consequences). Ninety three percent of 58 Bucharest respondents thought they had learned from the AEs that had occurred; this information was not available from the Italian hospitals.

Table 3 compares current IR procedures in the two Italian hospitals with the proposed IR procedure for the Romanian hospital in the light of ExpIR-RO experience. The characteristics of the future Romanian IR system (paper form only, periodic data collection, and immediate feedback after data collection) are closer to those of the Milan than Genoa IR system.

Table 1: Activity indicators in the hospitals participating in ExpIR-RO, according to department

Hospital and Departments	No. of discharges per month	No. of beds	Occupancy rate per month (%)	Average length of stay	No. of permanent staff/1 bed	
					Doctors	Nurses
Bucharest Hospital *						
Anesthesia and Intensive Care	190	33	65.6	3.4	0.7	1.0
Cardiology	161	28	106.6	5.3	0.5	1.2
General Surgery	178	39	140.4	8.0	0.4	0.7
Orthopedics	355	94	70.9	5.8	0.2	0.5
Radiology	-****	0	-	-	-	-
Genoa Hospital **						
General Surgery	39	17	79.5	5.9	0.3	0.8
Internal Medicine	83	30	73.0	7.9	0.2	0.5
Obstetrics and Gynecology	96	30	56.4	5.4	0.3	0.6
Neonatology	59	16	43.7	1.9	0.4	0.9
Radiology	-	0	-	-	-	-
Laboratory	-	0	-	-	-	-
Medical Management Department	-	0	-	-	-	-
Administration Department	-	0	-	-	-	-
Milan Hospital ***						
Intensive Care	2	6	64.3	3.1	1.5	3.0
Gastrointestinal-pancreatic-liver Surgery	59	24	86.2	9.1	0.4	0.6
Thoracic Surgery	56	42	59.0	7.2	0.1	0.4
Hematology	25	12	90.8	8.9	0.4	1.4

* Data refer to the first 7 months of 2007; ** Data refer to 2005; *** Data refer to 2007; **** not applicable

Table 2: Main information collected by incident reporting form, according to hospital

Item concerning the reported adverse event (AE)	Number of answers per item		
	Bucharest Hospital (58AEs/12 months)	Genoa Hospital (75AEs/12 months)	Milan Hospital (52AEs/3 months)
Person reporting AE	**58**	**75**	**52**
Doctor	48	41	26
Nurse	10	13	26
Midwife	0	20	0
Other	0	1	0
Type of AE	**58**	**75**	**52**
Diagnostic procedure	16	14	9
Patient fall	7	24	1
Drug prescription/administration	6	10	11
Surgical or therapeutic procedure	8	8	7
Inadequate functioning/positioning of device/machine	4	2	0
Confusion between two patients	4	0	1
Nursing care	0	15	13
Administrative procedure	2	0	3
Other	11	2	7
Contributing factors to AE	**156**	**73**	**71**
System-related	72	37	36
Staff-related	60	27	27
Patient-related	24	9	8
Severity of AE	**58**	**75**	**52**
Level 1	8	7	16
Level 2	3	8	9
Level 3	22	23	10
Level 4	14	21	12
Level 5	6	8	4
Level 6	5	5	1
Level 7	0	3	0
Level 8	0	0	0
Communication of the AE to the patient	**51**	**59**	**46**
Yes	37	38	20
No	14	21	26
Notification of the AE in the medical record	**53**	**60**	**44**
Yes	28	45	16
No	25	15	28

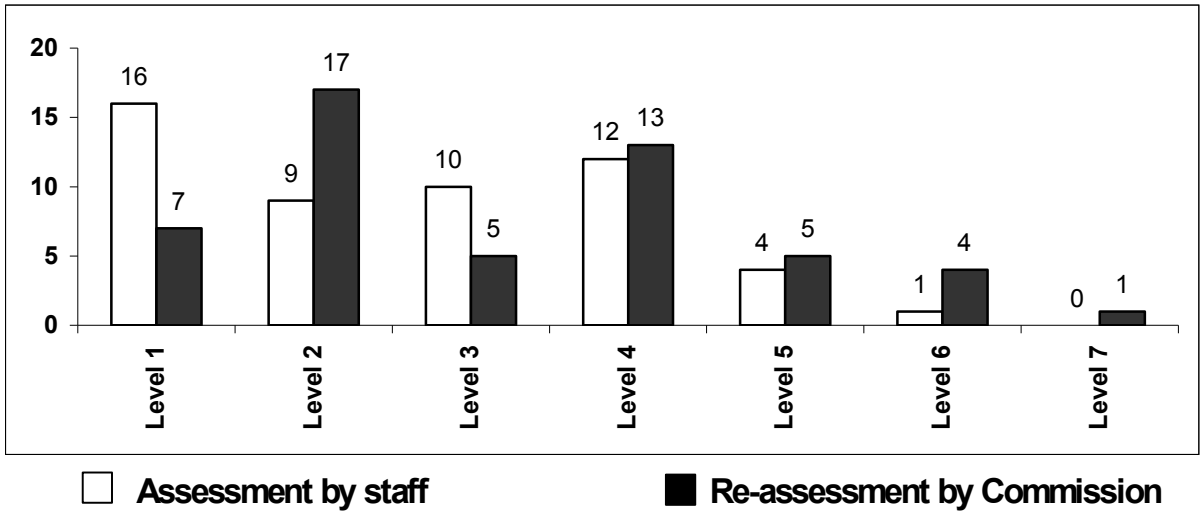
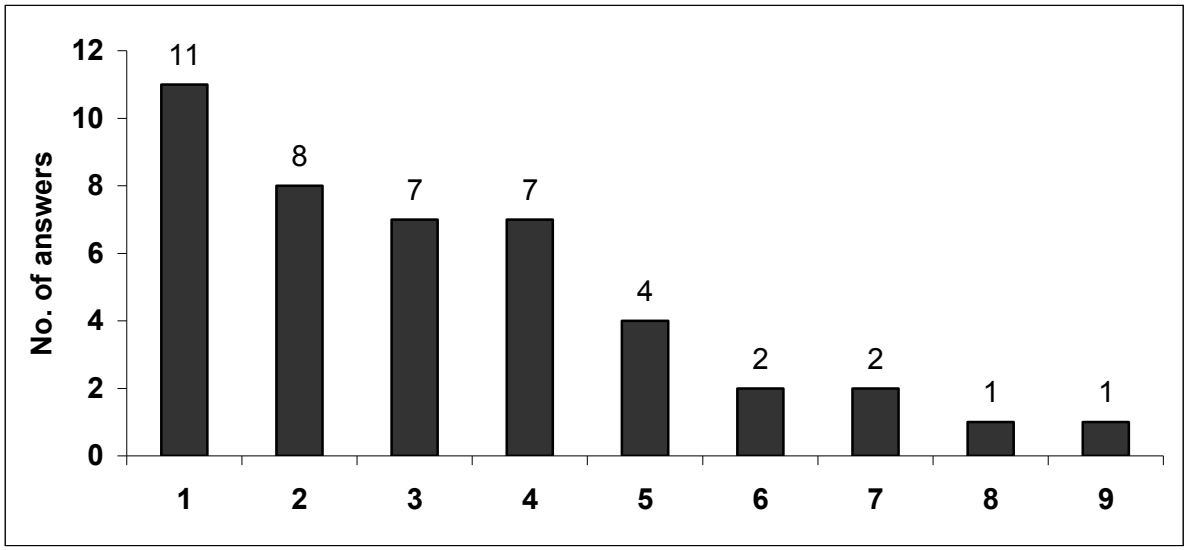


Fig. 1: Re-evaluation of the severity level of AEs in the Milan hospital



1 Improvement in personnel training
2 Review/modification of protocol/procedure
3 Improvement in communication with patient
4 Better availability of materials and equipment
5 Improvement in allocation of medical and nursing staff
6 Improvement in communication between departments
7 Better supervision of admitted patients
8 Better supervision of young doctors executing high risk medical procedures
9 Better prioritization of tasks

Fig. 2: Corrective measures proposed by staff who reported AEs at Bucharest hospital

Table 3: Comparison between current IR systems in the two Italian hospitals and the IR system proposed for implementation in the Romanian hospital post ExpIR-RO

Characteristics of IR system	Genoa Hospital	Milan Hospital	Bucharest Hospital
Participating Departments	Gynecology Neonatology	Departments that volunteered to report AEs	All Departments involved in ExpIR-RO+ any others that volunteer
Data collection method	Paper forms, on-line, or orally	Paper forms	Paper forms
Common or Department-specific IR Form	Common to all Departments	Common to all Departments	Common to all Departments
Data collection period	Reports accepted all year round	Reports accepted for few weeks twice a year	Reports accepted for a period of a few weeks
Transmission to Evaluation Commission	Sealed envelope, email or personally	Sealed envelope	Sealed envelope
First evaluation of AEs	Medical Management	Evaluation Commission (nursing staff manager + quality manager+ risk manager + medical consultant)	Quality Management Group
Frequency of evaluation	Each semester	Immediately after the end of the data collection	Immediately after the end of the data collection
Re-evaluation of severity level	No	Yes	No
Who decides corrective action?	Clinical Risk Commission (Hospital medical director + Risk Management Group including: risk manager, medical and nursing staff chief, quality manager, 3 department medical directors/medical consultants)	Evaluation Commission+ Department Medical Manager	Quality Management Group+ Department Medical Manager + Hospital Medical Management
Who gives feed-back to staff? How given?	Report on intranet, prepared by Risk Management Group + Quality Management Group	Evaluation Commission+ Department Medical Manager	Quality Management Group+ Department Medical Manager
Who evaluates efficacy of corrective action?	Risk Management Group + Clinical Risk Commission	Evaluation Commission	Quality Management Group

Discussion

Over two years the ExpIR-RO international pilot project tested a voluntary IR system in a Bucharest public hospital in comparison with IR systems in hospitals in Genoa and Milan. The Italian hospitals provided advice and the retrospective results of the initial tests of their IR systems. We compared data for the three hospitals, but acknowledge that the comparison is complicated by marked culture differences and also marked differences in hospital activities: the Bucharest and Milan hospitals are large teaching hospitals mainly treating difficult or complex diseases, while the Genoa hospital is small and generally treats simpler conditions often in day hospital regime; the bed occupancy rate of over 100% in Bucharest reflects highly intense use- or overuse- of hospital facilities.

The total number of AEs per month registered was fairly low (5 in Bucharest, 6 in Genoa, and 17 in Milan). The number of AEs per 1,000 hospitalization days per month is a more informative indicator as it considers the number of patients at risk, but could only be estimated for departments with beds. This approach underestimates AEs in the Bucharest and Genoa hospitals since AEs reported by Units/Departments with no beds (e.g. Radiology, Laboratory, Management and Administration) were excluded. Nevertheless, the AE rate of 15 Milan is much greater than the rates of 1 in Bucharest and 3 in Genoa.

Assuming that all caregivers in the participating Units of the three hospitals knew of the IR system, how to access the form, and what to do with it once completed, the large difference in AE rate suggests that data collection over short periods (a few weeks) followed by immediate feedback, as occurred in Milan, may better motivate staff to report AEs than continuous data collection with feedback every six-months as in Genoa.

As described by other authors (16), medication-related AEs are usually better reported than other AEs because they require immediate corrective action. In fact the proportion of drug prescription/ administration-related AEs was higher in Milan (21%) than Genoa (13%) and Bucharest (10%). However it is noteworthy that the four participating Units of the Milan hospital volunteered to participate, while in the other two hospitals management decided which Units should participate. Perhaps the grassroots approach of Milan may have motivated caregivers to report AEs more effectively than the top-down approach. It is also possible that many potential AEs (severity grades 1 and 2) were perceived as inconsequential or served no learning purpose and were therefore not reported by the Bucharest and Genoa hospitals (16). In fact Milan caregivers reported more potential AEs (48%) than Genoa (20%) and Bucharest (19%) suggesting underreporting in latter structures.

In Bucharest a large proportion (83%) of AEs was reported by doctors; figures for Genoa (55%) and Milan (50%) were considerably lower. In other studies most AEs were reported by nurses (9, 16). The Bucharest finding suggests that Romanian hospital nurses may have less autonomy or authority than in other countries and that doctors assume most of the responsibility.

In all three hospitals, diagnostic procedure-related AEs were among the commonest AE types. However in Genoa, patient falls were the most common AEs, possibly because this hospital has a large proportion of elderly patients. In Bucharest, most falls were from the bed (data not reported) suggesting the presence of old beds lacking anti-fall protection. In both Genoa and Bucharest, insufficient surveillance of patients by staff may have contributed to the falls.

In Genoa, patients were mainly elderly medical and surgical department cases (as well as mothers and babies in Neonatology), while in Milan they were cancer patients. Presumably these patients require more intensive nursing care than those in Bucharest, which would suggest why nursing care-related AEs were more frequent in these hospitals than Bucharest. In Milan, patients often receive complex therapeutic combinations (neo-adjuvant, adjuvant or palliative chemotherapy; target treatment; immunotherapy), suggesting why drug prescription/ administration-related AEs were commoner in this hospital than the other two.

In all three hospitals system-related failures (e.g. personnel shortage, inadequate training, insufficient communication or coordination, insufficient/inadequate facilities and equipment) were cited as the most common cause of AEs in accord with other experiences (9). Provider-related (e.g. inexperience, inattention, fatigue, inadequate surveillance, poor team co-ordination) and patient-related (e.g. linguistic or cultural barriers, severe condition, poor compliance) factors contributed less than system-related deficiencies. It is no surprise, therefore, that the main corrective actions proposed by respondents in Bucharest were system-related (revision/modification of protocols or procedures, improved training, better communication, and improved availability of materials and equipment). It should be stressed that, to be maximally effective, corrective actions should not be confined to one area but address all contributing factors to AEs. (17) Thus, corrective actions in the provider- and patient-related areas are also necessary (e.g. personalized training for inexperienced caregivers; use of cultural mediators to facilitate communication with patients of different language and culture; and greater involvement of the family in patient surveillance).

Most AEs notified in this study were of low severity, suggesting that staff properly understood the purpose of voluntary IR i.e. to detect potential and moderate AEs so as to take steps to reduce their risk of occurrence. Severity re-assessment by a Commission in the Milan hospital showed that respondents underestimated the severity of reported AEs. Another study found excellent agreement between respondents and other observers in terms of the severity of reported AEs, (14) although it seems important to occasionally check correspondence between internal and external assessors.

In Bucharest 73% of respondents reported AEs to patient and 53% entered them in patients' medical records. Potential AEs are rarely documented in medical records yet occur more frequently than

AEs and are useful for learning purpose (16). The decision to notify a patient or enter the AE in the clinical record depends on various factors such as: type and severity of AE, patient condition, ability to communicate bad news or apologize, and fear of disciplinary action. For these reasons it is unlikely that all AEs are reported to patients or entered in their medical records. Optimal reporting of AEs to patients requires training (18). Appropriate training of caregivers in these communication skills would mitigate anxiety. The participants in Bucharest did not receive training in conveying AEs to patients before starting the study.

A limitation of this study is that the results are unlikely to be generalizable to all Romanian public hospitals for several reasons including the fact that reporting was voluntary and it was a first-time experience in IR. It is likely that only a small fraction of the AEs that occurred were reported on the IR form. Higher reporting rates are associated with a more positive safety culture (8). Because of the low numbers of reported AEs and of the difficulty of exactly identifying population of patients at risk, we reported AEs according to a fairly crude method (rate of AEs per 1,000 hospitalization days per month).

The strength of the study is that, as far as we are aware, it is the first time a voluntary IR study has been conducted in the Romanian public healthcare sector. By the end of the project the Bucharest hospital decided to implement IR on a regular (periodic) basis in the departments involved in the project and other volunteer departments as well.

Some preventive measures to reduce future AEs have been implemented in Bucharest. Other essential steps (better provision of materials and allocation of nursing staff) may be implemented when the staff shortages and serious under-funding are remedied. It is essential to learn from AEs to improve the quality of care. Almost all Bucharest respondents said they had learnt from reported AEs. In this contest it is interesting that the number of reported AEs doubled in the second period of data collection compared with the first (39 versus 19). Thus we may perhaps be seeing the beginning of safety consciousness and the initiation of safety culture.

Finally we note that the Department of Public Health and Healthcare Management of "Carol Davila" University of Medicine and Pharmacy has set up post-graduate pilot courses on clinical risk management, inspired by the results of ExpIR-RO study. Other Romanian hospitals have contacted the project team for advice with the aim of setting up their own pilot IR systems. However, because the IR system has limitations, it needs to be supplemented with other methods for detecting clinical risk such as active surveillance of prescriptions by pharmacists, review of patient records, or use of administrative data for identifying AEs (6, 19).

Ethical Considerations

Ethical issues including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc. have been completely observed by the authors.

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