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Efficacy of an Education on Adverse Drug Reaction Reporting By Nurses in Nursing Homes: A Pre-Post Study

Fabbri S[1]*, Sichetti D[2], Di Giulio P[1]

[1]Turin University, Italy

[2]SC Farmacia Territoriale, Azienda Sanitaria Locale TO4, Chivasso, Italy

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***For Correspondence**

Stefania Fabbri, RN, MSc, Turin University, Italy, Tel: +393387765819.

E-mail: stefania.fabbri9@gmail.com

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ABSTRACT

Objective: To assess the efficacy of an educational intervention on nurses' skills in nursing homes (NHs) to identify and report adverse events related to drugs.

Methods: Multicentre pre-post study with a convenience sample of NHs from Turin who agreed to participate in the study. Nurses were asked to report unexpected problems of patients they cared for during the observation shift, the possible causes of these problems (clinical, organizational, drugs), and their perception of their avoidability. The adverse drug reactions (ADRs) reported was assessed with the Naranjo algorithm. Data were collected 3 weeks before and 3 weeks after an educational intervention based on a lecture, a discussion of cases and study of ad hoc material on drugs responsible for ADRs among the elderly.

Results: Sixty-two nurses from 7 NHs participated in the study; 26,834 patients/shifts were observed before and 23,883 after the educational course. The characteristics of patients with ADRs were comparable pre- and post-phase with the exception of age. After receiving the educational intervention, the number of ADRs reported doubled from 17 to 35 cases ($p<0.001$); 13/17 ADRs before and 32/35 after the course were known ($p>0.05$). Mean Naranjo scores increased from 2.7 (± 0.9) before to 3.3 (± 0.9) after the course ($p<0.05$), showing an increase of probable ADRs versus possible ADRs.

Conclusion: A specific educational intervention on drug surveillance seems effective in the short term in increasing NH nurses' skills of identifying and reporting ADRs.

KEYPOINTS

- Elders in NHs take on average 5 to 10 drugs more than elders in hospitals and are consequently more vulnerable to ADRs.
- ADRs are the 4th-6th leading cause of death and may be responsible for relevant social and economic costs. An education using lectures, discussion of cases and individual study may significantly increase the number of ADRs reported and their accuracy.
- A sizable participation of nurses indicates a strong interest in drug surveillance and research.

INTRODUCTION

With the steady growth of the number of elders, nursing homes (NHs) have become essential elements for care organisations

in most industrialized countries. To date in Italy, over 300,000 elders live in a NH, and 82% are over 75 years [1]. The elderly can be affected by several chronic illnesses and exposed to multiple drug therapies [2] with increased risk for drug interactions and inappropriate prescriptions: more than 40% of NH residents take at least one inappropriate drug [3,4]. Elders in NHs are prescribed on average 5 to 10 drugs (25% more than 10 drugs), which outnumbers drugs prescribed in hospitals [5], and are more vulnerable to adverse drug reactions (ADRs) [6]. An ADR is a harm associated with the use of a given medication in any use and at any dosage [7]. ADRs may be responsible for hospital admissions [8,9], and a recent meta-analysis showed that they cause 4.6% of deaths, representing the 4th most common cause of death [10], and increased social and financial costs [11].

Over 4,500 patients in 2 large north Italian hospitals were monitored by nurses who reported at least 1 adverse drug event (ADE) (medical occurrence temporally associated with the use of a medicinal product but not necessarily causally related) [7] for 53.3% of patients and an ADR for 3.5% of patients [11-18]. While significant literature has been written on ADRs in hospitals, less information is available for NHs. A prospective study in the USA showed that over a 4 year span, 65% of NH residents experienced at least one ADR [13].

In a recent multicentre Italian study on a sample of NHs and districts, 450 nurses observed their patients during 6 index days, reporting 519 events related to drugs or medical equipment, including ADRs [19]. Nurses are in the best position to identify and monitor ADRs [14,15] because of the time they spend with patients and their role in drug administration; however, nurse-reported ADRs are rare [16] despite the formal recognition in Italy of nurses' role in drug surveillance more than 10 years ago. Many factors may be responsible for this limited reporting: lack of recognition by doctors of nurses' role in drug surveillance; lack of knowledge on how to report or identify an ADR (partly due to a limited knowledge of drugs and their side effects), especially in multi-morbidity patients where the ADR may be confused with worsening of the illness [20].

Several studies have emphasised the importance of education to improve nurses' knowledge on drugs [21] and their reporting skills [18,22-24]. The courses lasted from 1 to 24 h, over 1 to 12 months, mainly consisting of educational lectures. In a Swedish hospital, after 24 lectures held by a nurse and a chemist, the ADRs reported increases from 0.4% of admissions to 11% [22]. In a subsequent study, the same author proposed a shorter course (6 meetings) with comparable results [23] and the recommendation to increase nurses' drug knowledge. The implementation of checklists with patients at risk for ADRs may help nurses to identify possible ADEs and start a treatment [25]. Information alone (letters, mails) did not improve ADE reporting [26,27]. Most studies were conducted in hospitals; only one study was published on NH nurses, which found that an hour-long lecture on ADRs and pharmacology followed by individual study improved nurses' knowledge, but the effect on ADE reporting was not assessed [28]. No studies have yet assessed the efficacy of an educational strategy in NHs.

AIM

To assess the efficacy of an educational strategy on nurses' skills to identify and report ADEs and ADRs.

METHODS

A multicentre pre-post study was conducted. Due to the difficult identification of ADRs in elderly patients with multi-morbid conditions, nurses were asked to report any unexpected problem or any unexpected event that would require a decision or an intervention. The problems were collected on all residents ≥ 65 years, and cared for by the participating nurses in the three weeks before and after the educational intervention. The 23 NHs that offer medical and nursing care for the Turin province were contacted by letter and phone to obtain authorisation to contact the nursing personnel for participation in the study.

Phase 1

Before (April-May 2013)

The project was presented in each NH, and a reference nurse was identified. Nurses were asked to report unexpected problems for three weeks during their shifts. Phone consultation to address any doubts or questions was guaranteed across the entire data collection period. To obtain information on the drug profile of the observed population, all of the drug therapies prescribed (including p.r.n.) were collected in an index day (treatments for chronic conditions are generally stable).

Education (May 2013)

The education consisted of: a) an interactive 4 h meeting on drug surveillance regarding the main drugs responsible for ADRs in the elderly (included dietary and herbal remedies surveillance) and a discussion of two cases based on those reported by the nurses; the nurses were trained on the use of the AIFA (Italian Agency of Drug) form to report a suspected ADR; b) the nurses had to study ad hoc materials on NSAIDs [29] and antipsychotics in the elderly [30], nurses' role in drug surveillance [31] and inappropriate prescriptions in the elderly [32]. A questionnaire with 72 multiple choice questions was administered to assess the knowledge gained. The educational meetings were conducted in each participating NH by a chemist specialised in drug surveillance. Each nurse was given 30 educational credits for the training.

Phase 2

After (June-July 2013)

Unexpected problems were collected for three weeks as in Phase 1.

Final meeting (July 2013)

A final interactive meeting was organised to discuss the most relevant ADRs reported.

Data collection

Unexpected problems were reported on a form adapted from a previous study [19] and piloted on 10 nurses for clarity and time needed for completion. The form was organised into 5 areas, and a form was completed for each problem, including the following information:

General information (number of patients cared for, date and shift–morning, afternoon, night);

- Patient characteristics (age, gender, co-morbidities);
- Problem description (type of problem, severity, possible causes, illness, organisation, drugs or devices and perception of avoidability of the problem);
- Drug (s) involved in the problem;
- Information on the nurse (professional experience, qualifications).

If the patient experienced the same problem in multiple shifts, it was reported for each shift. If the patient experienced more than one problem in the same shift and if the problems were apparently not associated (i.e., a fall and itching), two separate forms were completed. A general issue was a problem not related to drugs according to the nurses' judgment. Each problem associated with a drug was assessed by a nurse and a pharmacist; ADEs and ADRs were validated by the pharmacist according to WHO criteria [33]. The known ADRs (reported in the summary of product characteristics and/or monitored by the AIFA) were identified, and the strength of the association with the drug was assessed with the Naranjo algorithm [34]: a 10 question scale with a score ≥ 9 indicating a likely association of the reaction to the drug, 5-8 probable association, 1-4 possible, and <1 uncertain association of the reaction to the drug). Information to answer the last two questions (final outcome and biological fluids) was not collected.

Statistical analysis

Due to the lack of data on ADR reporting by nurses, the sample size could not be calculated beforehand. In the pre intervention phase, 26,834 patients/shifts were observed and 146 unexpected problems were identified (17 associated to drugs) during the 3 weeks. Expecting at least the double reported ADRs, to show a statistically significant difference with a power of 80% and a significance of <0.05, at least 37,202 patients/shifts had to be observed in the post intervention phase. A database using Microsoft Excel was created. The results are presented with percentages, means and standard deviations. To compare qualitative variables, the χ^2 test with Yates correction was used and the Fisher exact test, with the OpenEpi program, version 3.01. All the *p* values were considered to be statistically significant if ≤ 0.05.

Ethical aspects

Authorization for data collection was obtained by the medical directors of the NHs. This type of study does not require authorisation by the ethical committee. The anonymity of the nurses and patients was guaranteed as the data collection forms did not include any names.

RESULTS

Of the 23 NHs contacted, 7 (22%) from different areas of Turin agreed to participate in the study. All of the NHs guaranteed nursing care over 24 h with the exception of one facility that had a nurse on call during the night. The number of beds ranged from 95 to 170, and all of the NHs had a special care unit. All 62 nurses from the 7 NHs participated in the educational meetings (6 nurses could not attend the last meeting). The majority of nurses were female (89%), had a mean age of 33 years (± 8), a mean working experience of 3 years (range 6 months-22 years) and a mean experience in geriatric care of 2 years (range 6 month-19 years).

Each nurse in the observation shift cared for an average of 67 patients (median 49, range 38-170 patients) and, on average, 55 patients in the morning and afternoon shifts and 118 during the night without differences in the before and after periods (p=0.45). In **Table 1**, the drugs regularly prescribed to the 675 residents are presented (p.r.n. drugs were not reported). The residents were administered a mean of 7 drugs (± 3; range 0-23); 11 patients (1.6%) only one drug, 240 (35.5%) 2 to 5, 272 (40%) from 6 to 9, and 22% ≥ 10 drugs. Overall, 767 forms were completed: 399 (52%) before the course and 368 (48%) after (each form corresponds to a nurse's observation shift). In both phases, problems were reported mainly in the morning shift (61%, 42% before; 37%, 38% after); in the afternoon 46 (31%) before and 34 (35%) after and 27% during the night shift in both phases. Data on the number of forms and on patients with unexpected problems are presented in **Table 2.**

Table 1. Drugs prescribed to the 675 patients.

Drugs	Patients (675)	
	N	%
Cardiovascular drugs		
Anti-platelets	357	52.8
Diuretics	281	41.6
ACE-inhibitors	211	31.2
Beta-blockers	137	20.3
Nitrates	105	15.5
Anti-coagulants and Anti-thrombotic	100	14.8
Calcium blocking channels	78	11.5
Others~	88	13
Drugs for the nervous system		
Anti-psychotics	357	52.8
Benzodiazepines	257	38.1
Anti-depressants	208	30.8
Anti-epileptics	96	14.2
Others ◊	72	10.6
Gastrointestinal drugs		
Gastroprotectans	401	59.4
Laxatives	328	48.6
Others θ	85	12.6
Analgesics		
NSAIDs	132	19.5
Opioids	77	11.4
Vitamins and Dietary supplements	359	53.2
Acetaminophen	233	34.5
Anti-diabetics	116	17.2
Musculoskeletal	100	14.8
Respiratory	105	15.5
Antibiotics	74	10.9
Others †	309	45.7

Note: Other drugs include those prescribed to <10% patients:
~ digitalis and anti-arrhythmic;
◊ sedatives and anti-dementia;
θ anti-emetics and anti-diarrheics;
† statins, eye drops, thyroid, urological, steroids, skin and anticancer drugs

Table 2. Forms completed and unexpected problems reported.

	Before		After		Total	p value
	N	%	N	%	N	
Number of forms completed	399	52◊	368	48◊	767	0.028
Patients/shifts observed †	26834	53◊	23883	47◊	50717	0.037
Patients with problems	146	0.5~	98	0.4~	244	0.003
Patients with 1 problem	140	96	93	95	233	0.714
Patients with ≥ 2 problems	6	4	5	5	11	0.714
▪ Patients with drug related problems	17	12	35	36	52	<0.001
▪ Patients with illness related problems	98	67	53	54	156	0.039
▪ Patients with organisation related problems	22	15	4	4	36	0.006
▪ Patients with problems of unknown origin	9	6	6	6	15	0.989
Patients with severe problems°	52	37	40	43	92	0.411

Note: † Number of patients cared for by a nurse in each shift:
◊ Percentages calculated on total sums;
~ Percentages calculated on patients/shifts;
°Severe problems ≥ 7 (scale 0-10)

Patients for whom a problem was reported were comparable for age, sex, level of independence, time from admission, and co-morbidities, with the exception of dementia patients for whom a larger number of problems were reported in the after phase (66% before versus 94% after, p<0.001), and cardiovascular patients for whom fewer problems were reported (53% before

versus 35% after, p<0.05). After the education, the number of illness- and organisation-related problems decreased (from 129, 88% to 63, 64% p<0.001), although the majority of problems were associated with the residents' illnesses (73% before and 50% after). Organisational problems mainly included lack of information, lack of collaboration with the caregiver or errors in drug administration.

The nurses reported a wide range of problems (gastrointestinal, behavioural, respiratory, cardiovascular problems, fever, falls), mostly comparable in both phases, with the exception of pain (44/129 events, 34% before, and 6/63, 10% after, p<0.001), and of hypoglycaemia (the number of events reported increased from 13% to 35%, p<0.001) where the large majority in the after phase (17/22) was reported in one NH. Problems such as falls (12 cases), fever (23 cases) or seizures (3 cases) were never associated with a drug. Eighteen patients experienced a severe problem that required admission to the Emergency Department (12 cases before and 6 after; 2 were ADRs). Most problems (75/127, 58% in the before, and 42/63, 66% in the after phase) were successfully treated in the same shift, and in most cases the patient's problem had previously occurred to the same patient (82% in the before, and 81% in the after phase).

Drugs related problems and ADRs

After the education, the number of drug related problems doubled from 17 to 35 cases (p<0.001): 13/17 in the before and 32/35 in the after phase were ADRs known for that drug (p>0.05). Only one ADR (before phase) was considered to be incorrect (fever from wound infection without any association to a drug), while the other 6 problems, were reports of inappropriate prescriptions (under dosage, incorrect route, and time of administration). The mean Naranjo scores significantly increased after the educational intervention, and thus the number of probable versus possible ADRs (2.7 ± 0.9 before vs. 3.3 ± 0.9 after, p<0.05) increased. No ADR was uncertain; overall, the incidence of known ADRs (45) reported on the 675 residents was 6.6%.

The data collection forms after the educational intervention were more thoroughly completed as compared to before the intervention; in almost half of the forms (49%), relevant information on drug therapy, type of event, and the patients' clinical history were added. Clinical characteristics of patients with drug related problems were comparable in the two phases, including their drug profile with the exception of the mean age, which was lower in the after phase **(Table 3).** Patients with a drug related problem were prescribed on average 9 drugs, excluding p.r.n. drugs, compared to a mean of 7 ± 3 of the residents of the 2 NHs (p<0.001).

Table 3. Characteristics of the patients with drug related problems.

	Before (N=17)		After (N=35)		
	N	%	N	%	*p*
Age (mean ± SD)	88 ± 7		81 ± 7		**0.017**
Gender F	9	53	23	66	0.559
Level of independence					0.655
Not independent	4	23	12	34	
Partial	11	64	18	51	
Total	2	11	5	14	
Time from admission					0.706
≤ 1 month	-	-	1	3	
1-6 months	4	23	10	29	
≥ 6 months	13	77	24	69	
Clinical problems					
Dementia	9	53	21	60	0.853
Cardiovascular diseases	14	82	21	60	0.194
Cerebrovascular diseases	6	35	13	37	0.859
Diabetes	9	53	11	31	0.233
Musculoskeletal problems	3	18	9	26	0.766
Chronic Pulmonary diseases	2	12	11	31	0.232
Cancer	3	18	6	17	0.729
Others*	6	35	8	23	0.538

Note:* Psychiatric, liver and renal illnesses

Drug related problems are reported in **Table 4.** No significant difference was found before or after the educational intervention for the type of event including gastrointestinal problems (nausea, vomiting, diarrhoea), drowsiness and cardiovascular problems (hypo/hypertension, tachycardia), which were reported more frequently after the educational intervention. The 6 reported skin reactions were associated only with drugs: antibiotics (4/6) and "natural" products (2/6).

Most problems (13/17, 76.5% before and 23/35, 66% after) had previously occurred in the same patient. Although the difference was not statistically significant (p=0.33), the number of problems judged to be unavoidable decreased (from 18% before to 9% after). Twenty-one percent (11/52) of the drug related problems were judged to be avoidable, and 10% (20/192) of those related to other causes. After the educational intervention, the number of problems associated with psychotropic drugs (especially antipsychotics) and dietary and herbal products increased. The drugs responsible for the problems are listed in **Table 5.**

Table 4. Description of drug related problems.

	Before		After		
Problem	**N (17)†**	**%◊**	**N (35)†**	**%◊**	**p**
Gastrointestinal problems	5	29.4	13	37.1	0.811
Behavioural problems	4	23.5	6	17.1	0.862
Pain	3	17.6	3	8.5	0.618
Metabolic problems(hypo/hyperglycaemia)	3	17.6	3	8.5	0.618
Drowsiness	2	11.7	11	31.4	0.232
Skin reactions	2	11.7	4	11.4	0.669
Cardio/circulatory problems	1	5.8	4	11.4	0.892
Respiratory problems	-	-	2	5.7	0.813
Others *	2	11.7	7	20	0.729

Note: † The sum outnumbers the total as some problems were associated (i.e., pain and constipation);
◊ The denominator is the number of patients with drug related problems;
* Depression, bleeding, hypothermia, urinary problems, seizures

Table 5. Drugs responsible for the 52 drug related problems.

Drugs	**Before**		**After**		
	(N=17)†	**%˜**	**(N=35)†**	**%˜**	**p**
Gastrointestinal	6	35.3	2	5.7	0.018
Blood glucose lowering drugs/Insulin	2	11.7	5	14.2	0.854
Cardiovascular	2	11.7	6	17.1	0.924
Dermatologic	2	11.7	0	-	0.193
Antibiotics	2	11.7	4	11.4	0.669
Analgesics (NSAIDS, Opioids)	-	-	1	2.8	0.709
Dietary and herbal products	-	-	5	14.3	0.255
Psychotropic					
Antipsychotics	6	35.3	18	51.4	0.424
Anti-epileptic	1	5.8	2	5.7	0.54
Benzodiazepines	-	-	2	5.7	0.813
Anti-depressants	-	-	4	11.4	0.370

Note: † The number of drugs is higher than the events reported as more than one drug could be involved in the same event

In most cases (14/17, 82.3% before and 25/35, 71.4% after), the problem was associated with a single drug, mostly a chronic treatment, and in the other cases 2-4 drugs, mostly of the same class, without significant differences for problems associated with one or more drugs. Interventions ranged from stopping the involved drug (29% before and after), to changing the drug (6% before and 9% after), to modifying the dosage (23% before and after) without significant differences across periods. The median severity of the problems was 6 (range 1-10) before the course, and 7, and 5 after the course, respectively, for ADRs and problems related to other causes. More than 1/3 of the problems (35.6% before and 40.8% after) were severe (score ≥ 7).

DISCUSSION

In this study, differently compared to other studies of drug surveillance, the ADR reporting form was not used; instead, the nurses were asked to report unexpected problems. In fact, when an unexpected problem arises, a side effect or an ADR should be suspected. During the 6 weeks, unexpected problems were reported for 244 patients (36% of the observed patients and 2.5% of patients/shifts). The figures are comparable to those of another Italian study where unexpected problems were reported in 2.9% of patients/shift [19].

The population described is typical of NHs, with a higher prevalence of women with more than 80 years, dependent, on multi-drug therapies, and with cerebro/cardiovascular illnesses and dementia, which are all risk factors for ADRs [35]. After the educational intervention, the number of ADRs reported more than doubled and the accuracy of reporting increased. Discussion of cases is one of the more effective learning methods [36], while Lim showed that a brief lecture with individual study improved the NH nurses' often limited knowledge on drugs [28]: the author found that a knowledge base is essential to identify the relationship between drugs and events.

The incidence of ADRs in the present study was 6.6% and is much lower if compared to 65.4% hypothesized by Cooper after a multi-centre prospective analysis of clinical records over 4 years in US NHs [13]. Considering the complexity of the patients and the multi-drug treatments, including drugs at high risk for ADRs, a higher incidence of ADRs could be expected. However, the 45 ADRs identified are an important result considering that nurses in Piedmont in 2012 reported 33 ADRs [16]. Notwithstanding the variability of type, characteristic, and severity, the most reported ADRs are comparable to those reported by Opri et al. (behavioural and gastrointestinal disturbances, drowsiness) [18]. Overall, the nurses' vigilance increased, as not only severe ADRs were reported, compared to doctors who tend to report only the most severe ADRs [37].

The drugs at higher risk for ADRs in NHs include the following: central nervous system drugs (neuroleptics, benzodiazepines, etc.), cardiovascular drugs (antiarrhythmics, antihypertensives, etc.) and gastrointestinal drugs (antiemetics, laxatives, antidiabetics, etc.) [38], which are also responsible for ADRs in our study. Notably, while the number of ADRs reported increased for drugs discussed in the course, none of the ADRs were associated with anti-coagulants or anti-platelets (not addressed in the course), although these drugs were prescribed to 15% and 53% of residents, respectively, and are recognised as being among the main drugs at risk of fatal ADRs and responsible for more than half of ADRs [39]. This finding may indicate a relationship between knowledge on drugs and event reporting: nurses tended to report what they expected to observe. The association between ADRs and knowledge on drugs was explored in only one study [23]: yearly reports of a department increased from 30 by nurses and doctors to 39 only from nurses. Unfortunately, the authors did not describe which drugs were discussed during the course.

A problem is not associated with a drug unless the causal relationship is accepted and known; for example, none of the 12 falls were associated with a drug despite the well-recognised association with benzodiazepines [40], largely prescribed in the involved NHs (to 257/675 residents). Psychoactive drugs, namely antipsychotics, were responsible for 38% of the drug related problems in the NHs [41], and exponentially increased the risk of ADRs. Considering the large number of patients administered these drugs (375/675 residents), the expected prevalence of problems associated with these drugs is anticipated to be higher. Numerous cases of hypo/hyperglycaemia were rarely associated with a drug despite the well-recognised effect of drugs such as beta-blockers, thiazide diuretics, and some antipsychotics on metabolic balance [42].

For 6 ADRs, the key element was the inappropriate dosage or administration route, i.e., behavioural problems (agitation, delirium, sleep disturbances) for under dosage of the antipsychotic, blood glucose alteration for insufficient or incorrect administration of insulin, or oral blood glucose lowering drugs. The involvement of nurses in drug surveillance may increase ADE reporting, but may also increase the focus on patients' problems [37]. Perception of the preventability of ADRs increased, although significantly. Almost half of ADRs can be anticipated and thus avoided [43]. Attribution of possible causes and the perception of preventability are key elements to guide the decision process: if the causes of a problem are known, its prevention or resolution may be easier. The participation of all NH nurses may indicate a high interest in drug surveillance. The observation time was limited by the holydays, which prevented us from reaching the planned number of patients. However, the number of ADRs doubled in a population smaller compared to Phase 1. A follow-up study is needed to assess the long-term effects of the course.

CONCLUSION

Asking to observe patients' problems and identifying the possible causes (including drugs) may be an effective strategy to developing a culture of surveillance: a core component of nursing care and an essential component of drug surveillance. Despite the limited number of ADRs reported, an important aim was reached. In fact, ADRs reported over 6 weeks outnumbered those reported over one year in Piedmont. The nurses involved showed interest in drug surveillance and learning skills to correctly identify ADRs. Although the relevance of nurses' involvement in drug surveillance has already been acknowledged, the results of the present study further emphasize the need for concentrating efforts on increasing this involvement in the NH setting.

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