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RESEARCH ARTICLE

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Nurses competence in the reporting of medication-related incidents: An intervention study

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Abstract

Objectives: Less than 5% of all harmful medicine-related incidents (MIs) or adverse drug reactions received by the Spanish Pharmacovigilance system are notified by Registered Nurses (RNs). The main objective of this study was to determine the impact of a multifaceted institutional intervention (MII) in patient safety on the reporting competence of medication incidents of hospital RNs.

Design: One-group pre-test–posttest design.

Setting: Tertiary, public, teaching hospital in Spain.

Participants: A total of 139 RNs responded to pre- and postintervention questionnaires constituting the paired sample subjected to analysis.

Intervention: A MII, consisting of educational activities and materials, change in MI reporting form from paper to electronic and appointment of reporting support services, was designed and directed to all hospital RNs and midwifes.

Main outcome measures: Overall MIs reporting competence (OC) and its dimensions (attitudes, knowledge and skills) were measured through a synthetic variable (total OC value range: 34–170 points) by means of an electronic questionnaire.

Results: A statistically significant 7.96-point increase in OC from baseline to the final measurement was obtained (CI: 5.05–10.85). There was an increase of 7.38 points in the skills dimension (CI: 5.06–9.68). After the MII, 73.4% nurses improved their OC and 33.8% reported at least one no-harm MI postintervention compared to 4.4% pre-intervention ($p < .001$). A one-point increase in OC improved the probability of becoming reporter by 2.9% and a one-point increase in skills by 6.4%.

Conclusion: MIs reporting competence among RNs increased after a multifaceted institutional intervention, due to an improvement in the skills dimension. The MII was also effective in raising both, the rate of RNs who become reporters and the number of no-harm MIs reported.

[Correction added on 5 October 2021 after first online publication: The second and fifth affiliation were previously missing and have been added in this version.]

1 | BACKGROUND

Medication-related incidents (MIs) are the most prevalent group of healthcare-related problems (Expert Group on Safe Medication Practices (P-SP-PH / SAFE), 2006; Leape et al., 1991; Ministerio de Sanidad y Consumo, 2006). The Spanish national study on the adverse events associated with hospitalization "ENEAS" (Ministerio de Sanidad y Consumo, 2006) estimated that 37.4% of them are related to medication and that 4.1% of hospitalized patients experience adverse events associated with the use of the same.

Based on patient outcome, MIs can be classified as near misses, if they do not reach the patient: no-harm MIs, for events that reach a patient but without causing discernible harm, and harmful MIs, for events which result in harm to the recipient of a medication (World Health Organization, 2009). For the Spanish spontaneous reporting systems, near misses and no-harm MIs can be grouped as medication-related errors (MEs), while harmful MIs are considered to be adverse drug reactions (ADRs), which are defined as responses to a medicinal product which are unintended and cause harm. Reporting obligations behind these two categories are different. While healthcare professionals are advised to report MEs voluntarily to their institutional reporting systems, reporting of suspected serious, new or unknown ADRs to their national pharmacovigilance systems is mandatory by law (Directive, 2010/84/EU, 2010; Real Decreto577/2013, 2013).

Although they must be supplemented with other strategies, spontaneous reporting systems are a very efficient source of information about MIs, due to their low-cost and easy access; showing adequate specificity for capturing MIs with serious consequences for patients (Meyer-Massetti et al., 2011). If necessary, risk minimization measures for patients can theoretically be applied relatively quickly after ADR reporting (Edwards & Aronson, 2000). However, underreporting by healthcare professionals continues to be the main drawback of these systems, limiting their information capacity. The underreporting rate of harmful MIs is considered to be over 90% affecting both, primary healthcare and hospital settings (Hazell & Shakir, 2006).

RNs have the potential to be a valuable source of MI reports, since they spend about 40% of their working time on medication-related tasks (Agyemang & While, 2010), administering most of the medications in the hospital setting, being present when noxious effects occur and identifying different types of MIs, more so than physicians (Hall et al., 1995). Nevertheless, RNs constitute the healthcare professional category that provides the lowest number of harmful MI reports, with less than 5% of the total suspected ADRs registered at the Spanish Pharmacovigilance database (FEDRA). Additionally, the majority of said reports (73.2%) were notified by primary healthcare nurses (Salcedo de Diego et al., 2015).

The lack of awareness that RNs' appear to have about their professional role in pharmacovigilance, as well as their belief that they have inadequate pharmacology knowledge to identify ADRs, may explain the underreporting phenomena in the nursing profession, which highlights the need for pharmacovigilance training in nursing education (Bigi & Bocci, 2017).

With regards to focusing on MEs as a preventable source of harmful MIs, a systematic review (Vrbnjak et al., 2016) suggested that organizational barriers such as culture, the characteristic of the reporting system itself and management behaviours, along with personal and professional barriers such as fear, are considered limitations for MEs reporting. Therefore, anonymous, uncomplicated and efficient reporting systems, in addition to adequate support from the management level, are needed to improve and overcome underreporting.

Although numerous publications about improvement interventions in healthcare exist, recently, there has been criticized that many of them are not carefully designed and implemented (Marshall et al., 2017). Systematic development of interventions using a scientific approach which includes adapting both the content and format to the target population and its environment, is necessary for the intervention to be effective (van Bokhoven et al., 2003). The theory called "intervention mapping" (Bartholomew et al., 1998) has shown to be a useful method, not only for the development of interventions in the field of health promotion, but also for improvements in quality of care (van Bokhoven et al., 2003).

Most studies which address MIs reporting have been carried out following KAP models, which analyse knowledge, attitudes and practice of healthcare professionals as three different components of a construct (Hanafi et al., 2012; Herdeiro et al., 2004; Irujo et al., 2007; O'Callaghan et al., 2018). However, the concept of competence, defined as *the ability of individuals to integrate and apply the knowledge, skills and attitudes associated with the good practices of their profession to solve the problems that may arise in a specific context* (Ley 16/2003, de cohesión y calidad del Sistema Nacional de Salud, 2003), may be a better approach for designing, implementing and evaluating an intervention to change professional practice. This concept is in line with the existing education programmes at the university level (ORDEN CIN/2134/2008, de 3 de julio, por la que se establecen los

Strengths and limitations of this study

- To the best of our knowledge, this is the first work that assesses medication incidents reporting competence as a construct which integrates attitudes, knowledge and skills.
- The design and implementation of the multifaceted intervention were carried out systematically using a scientific approach.
- Strategies to increase the participation rate in before-after designs should be proposed.
- A mixed-method study considering a qualitative research approach could have been useful to explore reasons behind the low implication of nurses in adverse drug reactions reporting.

requisitos para la verificación de los títulos universitarios oficiales que habi-liten para el ejercicio de la profesión de Enfermero., 2009), as well as with methods used to assess nurses' professional performance (Juvé Udina et al., 2007; Meretoja et al., 2004).

The main objective of this study was to determine the impact of a multifaceted institutional intervention (MII) in patient safety on the reporting overall competence of medication-related incidents of RNs in a hospital setting.

Secondary objectives were as follows: to establish the intervention impact on each of the three competence-related dimensions (attitudes, knowledge and skills); to identify factors associated with a change in nurses reporting competence; to explore the MII´s impact on the proportion of nurses who improved their competence and who became self-declared MIs reporters; lastly, to describe the incidence of MIs reported by nurses at the institution before, during and after the MII.

2 | METHODS

2.1 | Design and population

This is a one-group pre-test–posttest design. The study population were all RNs and midwives working at a tertiary, public, teaching hospital in the outskirts of Madrid (Spain) and accessible by email ($N = 774$). Nurse Managers, researchers and lecturers were excluded.

The study was performed in three consecutive stages: a baseline or pre-intervention measurement, which was carried out between May and June 2013; the multifaceted institutional intervention, which occurred between the baseline and final measurements and a final measurement, which took place between April and May 2015.

2.2 | Sample size

The sample size estimation performed through Epidat 4.2, estimated for a 95% confidence level, 80% statistical power, considering a 4% pre-intervention MI notification rate (Salcedo de Diego et al., 2014) and a 14% postintervention (Ortega et al., 2008), concluded that 131 of participants responding to pre- and postquestionnaires were needed.

The pre- and postquestionnaires answers received from the same responder, were identified with the same unique automatic code number derived from their personal email address. Therefore, the participants´ responses could be paired, and those participants who answered both, pre- and postintervention questionnaires, were considered the units for analysis.

2.3 | Data collection instrument

A self-administered electronic questionnaire (NORMA) was designed ad hoc for the study to assess MIs reporting competence of RNs before and after the intervention. NORMA underwent a face and content validation (Salcedo de Diego et al., 2015) with the following steps: A review of the literature was performed for the creation of items. A panel of six experts assessed the relevance of the inclusion of each item in the questionnaire by calculating the position index; items with position index >0.70 were selected. The questionnaire was piloted by 59 RN different from the study participants. Finally, a meeting was convened with experts, in order to reduce the length of the piloted questionnaire through review, discussion and decision by consensus on each item. The instrument showed an adequate face and content validity and is easy to administer, enabling its institutional implementation.

2.4 | Outcome measures

The main outcome of the study was the overall MIs reporting competence (OC), defined as the integrated set of attitudes, knowledge and skills, which RNs develop to effectively notify MIs to the valid spontaneous reporting systems in the hospital setting. OC was measured through a synthetic variable constructed from the tally of the 34 items included in the NORMA questionnaire [28]. Each of the items was assigned a value between 1 and 5 points, thus permitting OC scores from 34 up to 170 points.

Each of the three dimensions, (attitudes (A), knowledge (K) and skills (S)) of the OC, had a different number of items as selected by the panel of experts during the questionnaire construction and validation. The lack of previous instruments to measure reporting competence resulted in the decision that the three dimensions should be equally represented in the OC. Therefore, it was necessary to apply a weighting factor to each dimension. Overall competence was determined as a continuous variable resulting from the formula:

$$OC = \sum (A1, A20) \times 0.56 + \sum (K1, K9) \times 1.26 + \sum (S1, S5) \times 2.27$$

Secondary outcome variables were as follows: weighted scores for each of the reporting competence dimensions (A, K and S, with possible scores ranging from 11 to 57 points for each dimension); proportion of RNs who improved their overall and dimensions reporting competence after the MII, defined as an increase in at least one point in the final questionnaire with respect to baseline; proportion of RNs who declared in NORMA having reported at least one MI in the last year (from these data, the conversion to reporter rate was calculated, meaning those RNs who became reporters during the MII).

In addition, incidences of MIs occurring from 01 January 2010 (the beginning of the institutional spontaneous incident reporting system records) to 31 May 2016 (1 year after the posttest) were collected from the hospital records and from the Spanish Pharmacovigilance System (Real Decreto 577/2013, de 26 de julio, por el que se regula la farmacovigilancia de medicamentos de uso humano, 2013). MIs were then classified according to patients' outcomes (no-harm MI, harmful MI or ADR, unknown).

2.5 | Hospital RNs characteristics

Socio-demographic, academic, work-related and professional characteristics of the RNs were also collected: gender (female, male); age; academic level in nursing studies (graduate: bachelor's degree in nursing; postgraduate: specialty in nursing, Master or PhD); bachelor's degree in other disciplines (yes, no); working experience in nursing; working experience in current unit; type of work unit (medical hospitalization ward, surgical hospitalization ward, specialized units: paediatrics, intensive care unit, emergencies, other); type of contract (permanent, temporary); working shift (fixed: always morning, evening or night or rotating: combination of at least two types of shifts); medication administration frequency (at least once a day, less than once a day); and self-declared training in patient safety (yes, no, not sure).

2.6 | Intervention design and implementation

The design and implementation of the intervention were based on the intervention mapping methodology (Bartholomew et al., 1998) and were structured in five stages:

1. Problem analysis stage: Barriers and facilitators for the intervention were identified at two levels: At the individual level, a descriptive analysis of the baseline questionnaires answered by all participants (not only the paired ones) was performed. At the institutional level, a set of interviews with their managers took place in order to identify the most appropriate available human, technological and material resources.
2. Design of the intervention stage: Methods and strategies with scientific evidence were selected after performing a literature review in English and Spanish (until 2013) on MEDLINE-PubMed, EMBASE, CINHAL and SciELO.
3. Pre-test stage: The educational materials designed were validated prior to their use, by the hospital´s Quality Assurance Unit and approved by the Risk Management Commission. The tools requiring any type of technological support were piloted in order to detect and correct any technical or operational failures.
4. Implementation stage: The multifaceted intervention finally performed at the institution, aimed to improve the attitudes, knowledge and skills of RN towards MI reporting, and lastly to increase their reporting incidence. It included the following set of strategies, presented here according to the chronological order in which they were implemented:
    - Educational activities and materials: A continued education course named "Safety in patient care: basic tools for analysis" with a duration of 2 days, including 3.5 hr of training in MIs reporting with a theoretical and practical approach, was offered to nurse managers and patient safety leader nurses. In 2014, the course was attended by 66 out of the 82 RNs invited. After receiving the course, those trained RNs delivered patient safety sessions in their own units, reaching out to 92% of the hospital units and 485 healthcare professionals. Nurse Managers and patient safety leader nurses met up every semester in 2014 and 2015 with the quality assurance unit in order to receive feedback from all reported incidents, including MIs. These strategies focused on increasing RNs knowledge and hands on skills on the reporting systems.
    - Change in MI reporting form format: The former paper incident report and ME report forms used at the hospital were both replaced by a new, electronic-only anonymous incident reporting system. It was accessible from the hospital´s intranet main screen on all hospital computers from 15 July 2014 onwards. With this action, an improvement of nurses' ability to report MI was intended.
    - A general research session to present the results of the pre-test questionnaire was undertaken at the hospital in May 2014, in order to raise awareness of the importance of reporting MI.
    - Appointment of reporting support services and feedback actions to reporters: A multidisciplinary team formed by doctors, nurses and pharmacists was created to give support and feedback to MI reporters, if required.
    - Some educational materials, such as USB pen drives with all the educational materials used in the courses and posters explaining the electronic reporting systems which included the contact details of the reporting support teams, were designed and distributed among RN and nurses stations as continuing education strategies.
5. Evaluation stage: included as part of the objectives of the study.

2.7 | Statistical analysis

Descriptive statistics of the study sample variables were conducted. To determine before-after change, McNemar test was used for paired samples in dichotomous or dichotomized categorical variables, and Student's *t*-test for paired samples in continuous variables. Bivariate analyses were done using the chi-square test (with exact Fisher correction, if needed) and the Student *t*-test for independent samples, depending on the nature of the variables. Multivariate logistic regression models were also undertaken, taking *becoming an MI reporter after the MII* as a dependent variable, as well as those which showed a significant association ($p \leq .20$) in the bivariate analysis as explanatory variables.

The significance level was established as $p \leq .05$. Confidence intervals were calculated at 95% accuracy. The programmes used for data processing were SPSS (IBM SPSS Statistics for Macintosh, Version 22.0. Armonk, NY: IBM Corp) and Stata (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

2.8 | Ethical aspects

The study was approved by the Ethics Committee and was conducted in compliance with the ethical principles stated by the Declaration of Helsinki and the applicable data protection law.

Patient and public involvement: This study did not involve patients.

3 | RESULTS

A total of 774 clinical RNs and midwives were invited to participate in the study. The baseline questionnaire was answered by 44.7% ($n = 339$) of them, while the postintervention questionnaire was replied to by 35.6% ($n = 276$). A total of 148 RNs (19.1%) took part in both measurements; nine of them were considered non-responders, defined as those participants who initiated but did not finish at least one of the questionnaires. Therefore, a total of 139 RNs constituted the final sample subjected to analysis. Most of them, 91.4% ($n = 127$), were female; mean age at baseline was 37.3 years (*SD*: 8.69); the percentage of participants who declared having received training in patient safety at baseline was 32.4% ($n = 45$) (Table 1).

Overall reporting competence (OC) showed a significant increase of 7.96 points (95% CI 5.05–10.85; $p < .001$), going from 112.4 (*SD*: 10.4) points before the MII to 120.4 points (*SD*: 13.9) after it (Table 2).

All analysed subgroups showed a significant increase in the main outcome OC, with the exception of those RNs who also held a bachelor degree in a discipline other than nursing (95% CI: −2.72; 14.39) and those who did not administer medication daily, (95% CI: −4.30; 11.59). The highest increments, over ten points in OC after the MII, were achieved by males (95% CI: 0.61; 21.1), by postgraduate RNs (95% CI: 1.64; 19.84) and by RNs who worked in units other than hospitalization (95% CI: 6.35; 14.43). This increment from RNs from non-hospitalization unit was significantly higher than their hospitalization colleagues (10.4 vs. 5.42 points; $p = .05$). No other differences in the studied categories were observed (Figure 1).

By dimensions, RNs' skills experienced a statistically significant increase of 7.38 points (95% CI: 5.06–9.68). As for the other dimensions, no significant changes were observed after the MII (Table 2).

Along the same line, as it occurred in OC, the increase in skills competence was significant in all studied subgroups except for the postgraduate RNs, those who held another university degree in addition to nursing and those who did not administer medication on a daily basis. RNs who reported being trained in patient safety at baseline, improved their skills competence significantly more than their untrained colleagues (8.58 vs. 4.51 points; $p = .029$). No other differences in the categories were observed (Figure S1).

Most nurses, 73.4% ($n = 102$), improved their OC after the MII. By dimensions, 51.8% ($n = 72$) of RNs improved their knowledge dimension; 51.1% ($n = 71$) improved their attitudes and 68.3% ($n = 95$) improved their skills. No statistically significant association was observed with any of the studied population variables (Table 3). The highest improvement, both for OC (77.6%) and skills dimension (72.4%), was achieved by RNs who reported in the postintervention questionnaire having received training in patient safety (Table 3).

Between 1 January 2010 and 31 May 2016, a total of 725 MI reports were notified by RNs to the hospital incident report system.

TABLE 1 Socio-demographic and work-related characteristics of nurse respondents pre- and postintervention

	Pre-intervention ($n = 139$)	Postintervention ($n = 139$)
Age, Mean (*SD*), years	37.3 (8.69)	39.3 (8.69)
Female, *N* (%)	127 (91.4)	127 (91.4)
Working experience, Mean (*SD*) in years		
Nursing career	14.9 (8.12)	16.9 (8.18)
Current unit	6.3 (5.26)	8.0 (5.25)
Academic level in nursing studies, *N* (%)		
Graduate (bachelor's degree in nursing)	123 (88.5)	119 (85.6)
Postgraduate (Specialty in nursing, Master or PhD)	16(11.5)	20 (14.4)
Bachelor´s degree in other disciplines, *N* (%)	16 (11.5)	15 (10.8)
Employees with fixed contract, *N* (%)	70 (50.4)	112 (80.6)
Type of work unit, *N* (%)		
Medical hospitalization ward	40 (28.8)	42 (30.2)
Surgical hospitalization ward	23 (16.6)	21 (15.1)
Special units (paediatrics. ICU. emergencies)	63 (45.3)	62 (44.6)
Other	13 (9.4)	14 (10.1)
Rotating shifts, *N* (%)	95 (68.4)	89 (64.0)
At least once a day medication administration, *N* (%)	122 (87.8)	124 (89.2)
Training in patient safety (self-declared), *N* (%)		
Yes	45 (32.4)	98 (70.5)
No	87 (62.6)	36 (25.9)
Not sure	7 (5.0)	5 (3.6)

The majority (94.6%; $n = 686$) were no-harm medication errors; 3.6% ($n = 26$) were harmful ME or ADR and in the remaining 1.8% ($n = 13$), outcome was unknown. April 2015 was the month with the highest number of reports ($n = 63$), including one harmful MI (Figure S2).

After the MII, self-reported proportion of MI reporters statistically increased from 5.8% to 36.7% [OR = 11.75 (95% CI: 4.30–44.91; $p < .001$)]. This improvement occurred at the expense of self-declaration of MEs reporting, going from 4.4% pre-intervention to 33.1% postintervention ($p < .001$). Change in self-declaration of suspected ADR from 2.2% to 8.0% did not result significant ($p = .128$).

A total of 47 RNs (33.8%) declared having become reporters during the intervention period. Multivariate logistic regression

TABLE 2 Overall competence and its dimension mean values and differences after-before intervention ($n = 139$)

	Pre-intervention ($n = 139$)	Postintervention ($n = 139$)	Difference (post–pre)
	Mean (*SD*)	Mean (*SD*)	Mean (95% CI; *p* value)
Overall competence	112.5 (10.4)	120.4 (13.9)	7.96 (5.05–10.85)*
Attitudes	37.3 (4.4)	37.6 (4.7)	0.24 (−0.84; 1.32).
Knowledge	41.4 (5.0)	41.7 (5.4)	0.34 (−0.89–1.57)
Skills	33.7 (8.7)	41.1 (10.7)	7.38 (5.06–9.68)*

*Statistically significant.

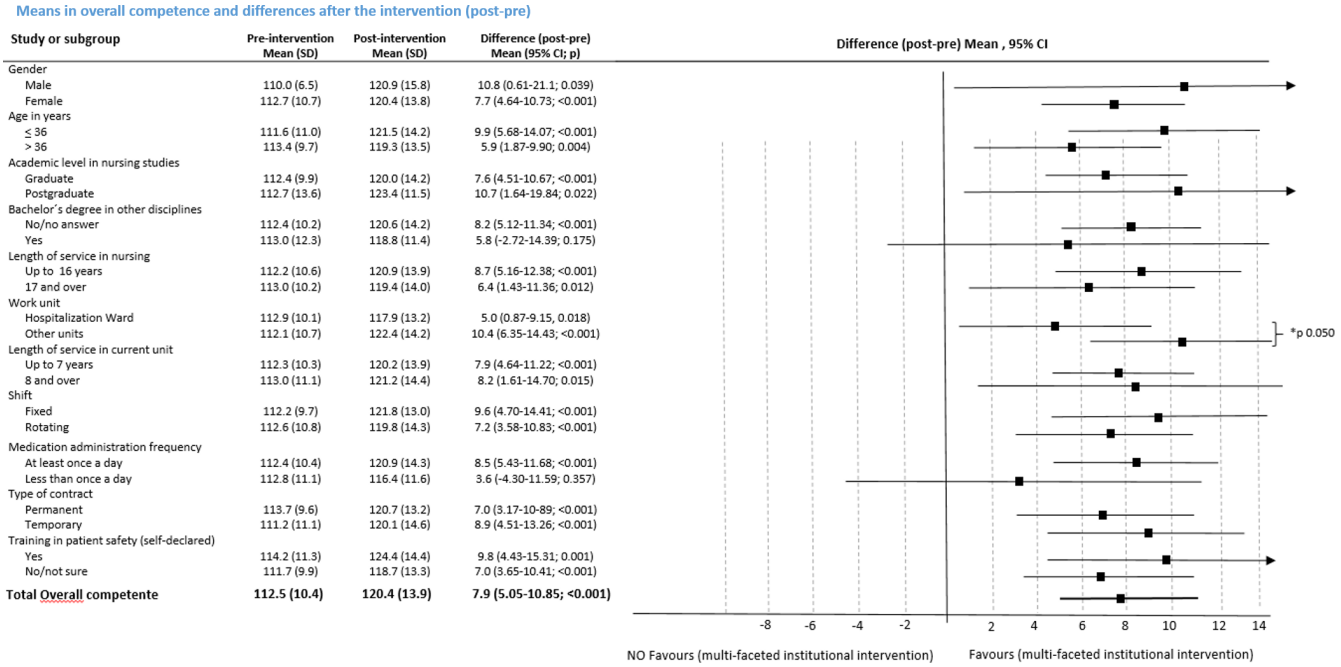

FIGURE 1 Means in overall competence and differences after the intervention (post–pre)

models significantly showed how one-point increase in the OC pre–post intervention difference, adjusted to the rest of variables, augmented the probability of becoming a reporter by 2.9%, while a one-point increase at skills dimension augmented the probability of becoming reporter by 6.4% (Table 4).

4 | DISCUSSION

Our study explored the impact that a multifaceted intervention on patient safety has on the competence of hospital RNs to report MIs. To the best of our knowledge, this is the first work that aims to assess reporting competence as a measurable construct, which includes attitudes, knowledge and skills.

The professional competence of RNs is considered to be a critical attribute for providing ethical, safe and high-quality patient care, thus making its measurement necessary (Flinkman et al., 2016). For this reason, designing and validating tools to measure RNs' competence in its different levels from general competence (Juvé Udina et al., 2007; Meretoja et al., 2004), to more specific ones, such as self-declared medication management competence (Johansson-Pajala et al., 2015; Sulosaari et al., 2011) has undergone a great deal of development over the last two decades.

As pointed out by Meretoja et al. (2004), assessing professional competence is crucial to identify educational needs and areas for development. Measuring baseline competence in our population allowed us to design a tailored intervention, taking into account its own population barriers and strengths, as well as those of the institutional environment where it was framed, which are necessary steps for the intervention to be effective (van Bokhoven et al., 2003; NICE, 2007).

Johansson-Pajala et al. (Johansson-Pajala et al., 2015) described the self-declared medication-related management competence and their involvement in pharmacovigilance activities. However, their definition of competence included only knowledge and skills, thus excluding the attitudinal dimension. Like in our study, training may increase pharmacovigilance competence, but it is not enough to modify the behaviour of RNs with regards to reporting suspected ADRs.

TABLE 3 Nurses who improved their overall reporting and skills competence after the intervention according to their socio-demographic and work-related characteristics (at the moment of improved evaluation)

		Overall competence		Skills competence	
	N total	*N* (%)	*p* value	*N* (%)	*p* value
Gender					
Male	12	10 (83.3)	.332	8 (66.7	1.000
Female	127	92 (72.4)		87 (68.5)	
Age in years					
<36	61	44 (72.1)	.847	43 (70.5)	.714
>36	78	58 (74.4)		52 (66.7)	
Academic level in nursing studies					
Graduate	119	87 (73.1)	1.000	82 (68.9)	.796
Postgraduate	20	15 (75.0)		13 (65.0)	
Bachelor´s degree in other disciplines					
No/no answer	124	91(73.4)	1.000	86 (69.4)	.558
Yes	15	11 (73.3)		9 (60.0)	
Working experience in nursing					
Up to 16 years	75	56 (74.7)	.848	53 (70.7)	.585
17 and over	64	46 (71.9)		42 (65.6)	
Work unit					
Hospitalization Ward	63	43 (68.3)	.250	41 (65.1)	.469
Other units	76	59 (77.6)		54 (71.1)	
Working experience in current unit					
Up to 7 years	73	57 (78.1)	.249	52 (71.2)	.470
8 and over	66	59 (68.2)		43 (65.2)	
Shift					
Fixed	50	37 (74.0)	1.000	32 (64.0)	.450
Rotating	89	65 (73.0)		63 (70.8)	
Medication administration frequency					
At least once a day	124	91 (73.4)	1.000	86 (69.4)	.558
Less than once a day	15	11 (73.3)		9 (60.0)	
Type of contract					
Permanent	112	83 (74.1)	1.000	77 (68.8)	.822
Temporary	27	19 (70.4)		18 (66.7)	
Training in patient safety (self-declared)					
Yes	98	76 (77.6)	.096	71 (72.4)	.115
No/not sure	41	26 (63.4)		24 (58.5)	
Improvement in competence (total)					
Yes	139	102 (73.4)		95 (68.3)	
No		37 (26.6)		44 (31.7)	

In a study on European postgraduate RNs (Wangensteen et al., 2018), they highly rated their competence in taking full responsibility of their actions, in cooperating with other healthcare professionals, in acting ethically and in reporting safety incidents. They found themselves less competent in identifying medication-related interactions, side effects and in establishing differential diagnoses, all of which are essential requirements for identifying and reporting ADRs. These results are also in line with ours, in the sense that RNs with the appropriate resources in place, overcome barriers when it comes to reporting safety issues which they may witness or commit, such as MEs, but they do not feel competent enough to diagnose and report ADRs. Further investigations to explain this phenomenon are needed in order to achieve greater implication of RNs in pharmacovigilance.

Nurses from units other than hospitalization increased their reporting competence more than those who conduct their professional activity in medical or surgical hospitalization units. Both paediatric units and emergency departments, considered as special

TABLE 4 Multivariate logistic regression models for becoming a reporter of medication incidents

	Odds Ratio	95% CI	*p* value
OC mean values differences (post–pre intervention)	1.029	1.000–1.058	.048
Gender	0.337	0.096–1.186	.090
Age (years)	1.007	0.964–1.051	.763
Training in patient safety (self-declared)	1.994	0.836–4.755	.120
Model parameters: $p = .024$; $R^2 = 0.063$; $n = 139$			
Skills dimension mean values differences (post–pre intervention)	1.064	1.020–1.110	.004
Gender	0.328	0.087 –1.228	.098
Age (years)	1.013	0.969–1.058	.581
Training in patient safety (self-declared)	1.744	0.721–4.215	.217
Model 2 parameters: $p = .002$; $R^2 = 0.093$; $n = 139$			

units, had specific patient safety teams comprised of medical professionals, nurses and pharmacists that were supported by the quality assurance unit, which periodically reviewed incident notifications, including MIs, making analyses and implementing improvement strategies in their units. These patient safety teams were never constituted in hospitalization units, which could explain the differences in results between the respective groups. These findings differ from those found in an Australian study, which found that a multicomponent intervention was able to significantly increase the spontaneous MI reporting by RNs who worked at hospitalization units, but not in special units (Kingston et al., 2004). Nonetheless, it seems that culture has a strong impact on reporting behaviours, so these studies must be interpreted with caution due to the different environments in which they were conducted (Fung et al., 2012).

Apart from having received patient safety training, this research study was unable to identify differences in competence changes associated with the study population's socio-demographic or work-related characteristics. These findings are similar to other studies that were also inconclusive when trying to establish associations between gender, age, professional experience or academic training in incident reporting, including MIs, which points towards an absence of relationship between them (De Angelis et al., 2016; Fung et al., 2012; Hanafi et al., 2014). Ekman et al. found greater knowledge and greater involvement in ADRs reporting in RNs with over 20 years of experience with respect to the youngest (Ekman et al., 2012). However, the study by Johansson-Pajala (Johansson-Pajala et al., 2015) also conducted in Sweden, only found a relationship between pharmacovigilance training and the competence of RNs.

Nevertheless, the small sample size in some categories, such as males, participants with other academic studies in addition to nursing or professionals who do not administer medications on a daily basis, could help explaining the absence of differences in the main results according to the characteristics of the professionals, resulting in very wide and, therefore, imprecise confidence intervals.

According to the results of RNs' self-reporting of MIs in the questionnaire, as well as the registry of incidents reports, it could be deduced that the multifaceted intervention had an important impact on improving MI reporting, which is especially relevant in the case of no-harm MEs. This fact is widely supported in the literature. Of special interest, are the findings by Abstoss et al. (2011) and Hession-Laband and Mantell (2011) in which they correlate an increase in the number of reported MIs, with a decrease in the incidence of ADRs, which is to say, a real improvement in patient safety. However, our MII showed no effect on the reporting of ADRs. These results are in line with the review by Bigi and Bocci (Bigi & Bocci, 2017), which suggested that nurses should be provided with specific training to refresh their knowledge of Pharmacology, in order to increase ADRs reporting. Nevertheless, this study was focused, not only on knowledge, but also on reporting competence, as it is an attribute that is deemed to be necessary and precursor to the action of reporting specific MIs.

4.1 | Limitations and implications for nursing education, research and practice

Although the response rates for both questionnaires assessed independently are above the 31% of the average response rate attributed to studies with electronic questionnaires, weekly reminders, which offer incentives and are personally addressed (Sánchez-Fernández et al., 2009), a limitation to highlight was the low participation rate in the before–after design. This could be due in part to the loss of subjects between the two measurements. Some unmeasured reasons could explain this fact: RNs who left the institution in the study period, discontent with the institution, a bad experience in the baseline questionnaire or in relation to MIs reporting, as well as the occurrence of other concomitant investigations that could exert an effect of fatigue or saturation among RNs. The profile of non-responders is unknown, and therefore, the reasons for the refusal of the subjects to participate could not be explored in the study. Due to the fact that paired subjects could be more motivated to report than non-responders, a selection bias that could affect the external validity of the study, cannot be ruled out.

Study designs without a control group have some intrinsic limitations which may affect the internal validity of their results. On the one hand, learning of the measurement tool could influence the improvement in results of the postintervention questionnaire. A period of 2 years between measurements is considered sufficiently long to ensure that said learning effect of the data collection instrument has not occurred. Having said this, a 2-year interval between pre- and posttest measures, it is a long period that works against the maturation effect which, therefore, cannot be ruled out in this study. On the other hand, about the history effect, no external factors such as other interventions or the media influence, which would be reflected, not only at the study level, but also at a higher level like a

change in MI reporting rates registered in the Community of Madrid, were observed [13]. Although a randomized clinical trial would have provided the most evidence to determine the effectiveness of an intervention on a phenomenon, some ethical, methodological and even logistical reasons rendered the selection of such a design unfeasible.

The main criticism of most interventions carried out for quality of care improvement is their lack of methodological rigour, which could contribute to the dubious effectiveness of the intervention performed (van Bokhoven et al., 2003). Therefore, one of the strengths of this research is the fact that the design and implementation of the intervention were carried out systematically using a scientific approach (Bartholomew et al., 1998). However, multifaceted interventions, such as this one, justified by being more effective than those based on a single strategy, cannot always establish which specific aspects of the MII are the most effective and efficient, which is a limitation that needs to be assumed.

It appears necessary to take a closer look at the reasons behind the low implication of RNs in ADR reporting. As previously stated, a recent study showed that RNs do not feel competent enough as to diagnose and report ADRs (Wangensteen et al., 2018). A qualitative research approach on this issue focused on a deep analysis of interviews with RNs, and other health professionals and institutional leaders such as the one recently done in India (Gajjar et al., 2017) could help to better understand this phenomenon in order to guide the planning and implementation of future interventions.

Further, addressing underreporting by RNs should be a priority for the near future, especially considering the new responsibilities for Spanish RNs as medication prescribers. The last national regulation on the matter (Real Decreto, 1302/2018) establishes that RNs, in the exercise of their professional activity, may indicate and authorize the dispensing of medications subject to medical prescription, in accordance with protocols or guidelines of clinical practice. As a new responsibility for the nursing profession, it seems imperative to include specific pharmacovigilance contents in both, undergraduate and postgraduate university programmes, as well as continuing professional development training. These initiatives have already obtained good results in other European countries, showing that nurses have positive attitudes, skills and knowledge about pharmacovigilance and ADRs reporting and are ready for their role in pharmacovigilance practice after they complete a prescribing qualification course (Schutte et al., 2018).

5 | CONCLUSION

The reporting competence of MIs among RNs increases after the implementation of a multifaceted institutional intervention. This change can be explained by RNs' improvement in the skills dimension, which is associated with having received patient safety training. The MII is also effective in increasing the proportion of notifying RNs and in improving the reporting rate for reported no-harm MEs but has no effect on the reporting rate for harmful MIs or ADR.

Addressing underreporting by RNs appears to be a priority for the immediate future, especially due to RNs' new role as medication prescribers in Spain. Preventing patient injury caused by medicines should be considered a goal among all healthcare professionals, including RNs. Therefore, the reporting of suspected MIs, particularly ADRs, should be recognised as a way to contribute to patient safety and, as such, should become a responsibility in nursing practice.

CONFLICT OF INTEREST

None of the authors have competing interests to be declared.

AUTHOR CONTRIBUTIONS

ISD, PSG and BRA conceived and designed the study. BRA, PSG and ISD performed the statistical analysis and interpreted the results. BAG and ISD contributed to the acquisition of data. ISD, PSG and CPH wrote the manuscript. All authors contributed to drafts of the article and provided final approval of the version to be published, accepting accountability for the integrity of the article. All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (https://www.icmje.org/recommendations/)]: substantial contributions to conception and design, acquisition of data or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content.

ETHICAL APPROVAL

The study was approved by the Ethics Committee at Hospital Universitario Puerta de Hierro Majadahonda (Spain) and was conducted in compliance with the ethical principles stated by the Declaration of Helsinki and the applicable data protection law. Responding to the anonymous questionnaires was considered an implicit acceptance for the study participation. Written consent form from the nurses' participants was not specifically requested, as approved by the Ethics Committee. Participants consent for publication was not required.

PATIENT AND PUBLIC INVOLVEMENT

This study did not involve patients. For the design of the questionnaires and the multifaceted intervention, opinions and acceptance from the institutional nursing managers were considered and obtained. Dissemination of results was carried out through institutional quality and safety training programmes, communications in national and international scientific conferences and publications in scientific journals.

DATA AVAILABILITY STATEMENT

Extra data about the design and implementation of the multifaceted intervention as well as all secondary objectives results and tables are available by emailing BRA (see correspondence details).

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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