A study of the prevalence of adverse events in primary healthcare in Spain

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Background: Healthcare practices involve risks for patients, but there has been little research to date on the occurrence of adverse events (AE) in primary care (PC). The frequency of AE in PC in Spain, the factors that contribute to their occurrence, their severity and their preventability, were analysed. **Methods:** Observational cross-sectional study was carried out in 48 PC centres in 16 regions of Spain. PC professionals were asked to assess whether the AE was caused by the healthcare or if it was an expectable consequence of the patient's underlying condition. A total of 452 healthcare professionals who attended 96 047 consultations were involved. **Results:** A total of 773 AE were identified, so that the point prevalence of AE was 0.8% [95% confidence interval (CI) 0.76–0.85]. A majority of AE (64.3%) were considered preventable and only 5.9% were severe, usually related to medication [odds ratio (OR) = 4.6; 95% CI 2.1–10.3]. The most frequent causal factor of the AE was associated with medication (adverse drug reactions and medication errors), but problems in communication and management were at the root of many of the AE. Nurses reported more preventable AE (OR = 1.9; 95% CI 1.2–2.8). **Conclusion:** In spite of an AE being less damaging in PC, large numbers of patients and professionals suffer their consequences each year. An awareness of the magnitude and impact of AE is the first step on the road to the cultural change necessary for achieving safer healthcare.

Introduction

One of the basic requirements of quality healthcare is to ensure that the treatment received by patients does not cause them any harm. However, sometimes patients may experience an adverse event (AE) as an unanticipated, unforeseen accident causing them some harm or complication which is a direct result of the care dispensed and not of their illness.

Since primary care (PC) is the first point of contact between patients and the healthcare system, an error at this level can lead to a succession of unnecessary tests and treatments that could harm the patient.

Studies have reported errors per patient encounter ranging from 0.2% to 7.6%; of these, 39.3% have caused the patient harm.[1–5] The most frequently found cases in all of the studies are related to the prescription of medications, with figures nearing 40%.[6,7] Of this 40%, up to 20% of the cases could be considered preventable.[8] In addition, a prescription error rate of 7.5% has been found in the PC context.[6] Diagnosis-related errors are also considered to be a major source of AE. The most frequent of all is a wrong diagnosis.[9] The combination of diagnostic errors with prescribing-related effects is responsible for 13.6% of the effects found.[10] Lastly, studies have suggested as a third contributory factor of AE, poor communication among professionals and patients.[11,12] Research estimating the clinical consequences of errors for the patient is lacking in PC, since a majority of the studies to date are based on voluntary reporting systems.[13–15] However, the identification of AE in PC is particularly more complex, as many of them go undetected.[16]

Professionals in PC work in a context where they deal with unavoidable uncertainty, of high demand for care and with a high rate of consultations from patients with a wide range of heterogeneity in their pathologies and psychosocial characteristics. In many cases, patients seek medical care in the initial stages of their illness, with symptoms and signs that are still poorly defined, and the healthcare professional must maintain a complex balance between clinical skills and the rational use of diagnostic tools.[17] Patients are most commonly over 65 years, often with multiple pathologies of a chronic nature and polymedicated—a set of circumstances involving greater risk of AE.[18,19]

The Spanish PC context is a highly appropriate one for carrying out a study of the frequency, causes and impact of AE. The rate of frequency in Spain is the highest in Europe[20] with an average of 9.5 medical consultations per person in a year (Organisation for Economic Co-operation and Development (OECD) mean 6.8). Health centres are staffed by multidisciplinary teams made up of general practitioners (GP), paediatricians, nurses, and in some cases even social workers, midwives and physiotherapists. According to the principle of continuing care, PC also includes emergency attention and even in-home care, as the highest expression of accessibility and equity.[21] However, no studies to describe AE in Spanish PC had been carried out till today.

The aim of this study was to describe the nature of AE in PC in Spain, their contributory factors, consequences and preventability.

Methods

Observational cross-sectional study with a point prevalence survey based on the diagnosis of an AE in health centres' consultations in 16 of Spain's 17 autonomous regions was carried out over a 2-week period (11–24 June 2007).

The study (called APEAS) was funded by the Quality Agency of the Spanish National Health Service, and approved by the Ethics Committee at the Saint Joan University Hospital.

Settings and sample

A convenience sampling of 48 health centres (in both rural and urban areas) was carried out, resulting in the selection of one health centre in each Health District, and no more than five per autonomous region. To be included in this study the minimum staffing level of these centres was three physicians, two nurses and a paediatrician, enabling a total of at least 4500 consultations per day to be reached for the whole sample. These consultations include all type of patients attended usually in PC without exclusions.[22] Nurses were included because in Spain they are responsible for specific follow-up care for diabetic and hypertensive patients. All professionals participated under opportunistic and voluntary bases.

Data collection and variables

Identification of AE (defined as any incident causing harm to the patient and related to the healthcare provided) was based on a reporting system approach. PC professionals (PCP), after visiting the patient, had to report (on the APEAS form) any condition that might indicate an AE, incidents which did no harm, disease complications or problems related to the patient themselves (treatment failure, delay in consultation, etc.). The report required assessment on a six-point scale referring to evidence of whether the harm was caused by the healthcare or was an expectable consequence of the patient's underlying condition, any causal factors identified, and whether the AE was preventable. Events had to be active, under treatment or at an after-effect stage. Threshold for the preventability score (on a six-point scale referring to evidence on whether the AE could have been avoided) was ≥4. Impact was assessed on the basis of clinical repercussions and healthcare needs after the AE. AE related to a permanent injury or death was considered as severe, while those resulting in a new consultation, surgical treatment, medication or admission to a hospital were considered moderate. Confidentiality was ensured, since no patient's personal data were entered in the APEAS form.

The APEAS form used for the reporting was a version of the University of Washington safety questionnaire,[23] adapted to the Spanish PC context (see Supplementary Appendix). Fifteen PCPs participated in a consensus session for reviewing the original questionnaire, suggesting new situations or changes for adapting the instrument. A pilot study was carried out to assess the construct validity of the APEAS form. Moreover, the scales of causality and preventability were the same that those used in the study carried out in Spanish hospitals,[24] in which, with the same training programme, the κ-value was, on average, 0.65 for causality and 0.55 for preventability. To ensure the successful application of the APEAS form, a sample group of PCPs from each autonomous community participated in an 8-h training programme, which included a review of operational definitions and the discussion of more than 20 examples. Afterwards, these representatives were required to train other colleagues, and for this purpose they were provided with educational materials comprising of presentations with terminology adapted for the study and a procedure manual.

Data analysis

To estimate the prevalence, the number of patient consultations was used as denominator. A univariate analysis was carried out for the description of the sample (average, mean, standard deviation and interquartile spread for continuous variables and frequencies for categorical variables), and a bivariate analysis for establishing relationships between the variables (by means of χ^2 for comparing percentages). To explain the severity and preventability of the AE a logistic regression model was applied. The hypotheses were compared on a two-way basis, with a 0.05 significance level, except in the case of the logical regression model (forward stepwise logistic regression model using likelihood ratio test), in which a P-value of under 0.05 was used for inclusion and of under 0.10 for exclusion. The statistical analysis was carried out using the SPSS Version 15.0 statistics program.

Results

The final sample consisted of 96 047 consultations (whatever their purpose) with 452 PCPs; 249 (55.5%) being GPs or physicians in training (PT), 152 (33.6%) nurses and 49 (10.8%) paediatricians. A total of 40 963 (42.6%) patient visits were for males and 55 084 (57.4%) for females. Of the 96 047 consultations, 61 049 (63.5%) were with physicians, 25 436 (26.5%) with nurses and 9563 (10%) with paediatricians.

A total of 2059 reports were registered, corresponding to 1932 different consultations (table 1). There were 716 incidents without harmful consequences and 53 complications judged by the PCPs as being due to patients' intrinsic conditions. A total of 1074 injuries were identified (AE) in 971 different healthcare consultations (6.7% of patients presented more than one AE). Therefore, the point prevalence of AE detected in PC was 1.1% [95% confidence interval (CI) 1.0–1.2].

As regards the source of the AE, 773 (73.1%) occurred at a PC health centre, 246 (23.3%) in specialized care, 32 (3.0%) in hospital emergency departments and 7 (0.7%) at dispensing pharmacies. Thus, the point prevalence of AE directly related to PC was 0.8% (95% CI 0.8–0.9).

A majority of cases, in which professionals reported AE, were patients with chronic conditions (see Supplementary table 1). AE were identified in 231 (34.5%) hypertensive patients, 117 (17.5%) diabetics and 38 (10.3%) neoplasia patients. These data represented a higher frequency than expected of these patients in the sample ($P < 0.0001$). On exploring the pattern of the degree of seriousness of the AE among the patients who had more frequent intrinsic risk factors (hypertension, diabetes, obesity, hypercholesterolaemia and depression) it was found that there does not seem to be any relationship between the more serious AE and any risk factor in particular.

Nature of the AE

About 55.5% (429) of the AE stemmed from problems with the medication prescribed; 17.1% (132) involved a worsening of the clinical course of the underlying disease; 7.8% (60) involved complications from a medical procedure; 7.4% (57) involved healthcare-related infection; and 6.1% (50) stemmed from problems with the care dispensed (wound cures, catheter care, etc.). The most common clinical consequence of AE was a worsening of the course of the underlying disease (table 2).

Contributory factors

The most common causal factors of AE reported by professionals were medication-related (215, 27.8%), but communication problems (190, 24.6%) and the way the care was delivered (168, 21.7%) were also at the root of many such events (see Supplementary figure 1).

Consequences of the AE

Most AE led to only temporary injury, and in many cases the healthcare was not affected (215, 27.8%) or only involved further observation or surveillance in PC (225, 29.1%). In another 113 (14.6%) cases additional treatment was required, and 34 (4.4%) were hospitalized. The AE identified by nurses were more serious than those detected by other PCPs, and those detected by physicians were milder. None of the AE identified by paediatricians were severe (table 3).

Table 1 Prevalence of patients with AE by type of professional

Professional category	AE	Consultations	Prevalence (%)	95% CI
GP and PT	478	61 049	0.8	0.7–0.8
Nurse	254	25 436	1	0.9–1.1
Paediatrician	41	9563	0.4	0.3–0.5
Total	773	96 047	0.8	0.8–0.9

GP: General practitioner; PT: physician in training; AE: Adverse events

Table 2 Nature of AE

	n (%)
Worse clinical course of the underlying disease (reason for consultation)	132 (17.1)
Nausea, vomiting or diarrhoea secondary to medication	81 (10.5)
Pruritus, rash or skin lesions reactive to drugs or dressings	49 (6.3)
Drug-related neurological alterations	41 (5.3)
Other secondary effects of drugs	35 (4.5)
Drug-related discomfort or pain	28 (3.6)
Systemic allergic manifestations	28 (3.6)
Surgical wound infection	25 (3.2)
Pressure ulcer	25 (3.2)
Local effects or fever after vaccination or drug administration	25 (3.2)
Need to repeat the procedure or visit	24 (3.1)
Poorly controlled glycaemia	23 (3.0)
Haemorrhage or hematoma related to surgical operation or procedure	22 (2.8)
Drug-related hypotension	22 (2.8)
Poorly controlled blood pressure	21 (2.7)
Drug-related headache	18 (2.3)
Suture dehiscence	17 (2.2)
Others	157 (20.3)
Total	773 (100)

Table 3 Severity of the AE by professional category

	Severity, n (%)			Total
	Slight	Moderate	Severe	
GP and PT	287 (60)	167 (34.9)	24 (5.0)	478 (100)
Paediatrician	23 (56.1)	18 (43.9)	0 (0.0)	41 (100)
Nurse	135 (53.2)	97 (38.2)	22 (8.7)	254 (100)
Total	445 (57.6)	282 (36.5)	46 (5.9)	773 (100)

In the logistic regression model carried out to explain the severity of the AE (slight vs. moderate or severe), AE whose main contributory factor was associated with diagnosis problems involved more risk of being severe than those related to medication (OR = 4.6; 95% CI 2.1–10.3). AE due to communication gaps (between professional and patient or among professionals) were also more severe than those related to medication (OR = 1.5; 95% CI 1.0–2.2). Likewise, the nature of the AE was related to its severity in such a way that healthcare-related infections (OR = 3.9; 95% CI 1.6–5.8) and care problems (OR = 4.1; 95% CI 2–8.5) were more severe than medication-related AE. Women were less seriously affected by AE than men (OR = 0.7; 95% CI 0.5–1). Neither PCP' category or their experience (in years) was significant when included in the model; nor was patient's age.

Preventability

About 8% (62) of the AE were considered completely unpreventable, 27.7% (214) scarcely preventable and 64.3% (497) preventable. Table 4 shows the preventability of AE by their nature and PCPs category. Preventability was also related to severity, in such a way that slight AE were 60.4% preventable, moderate AE 65.2% preventable and serious AE 64.3% preventable (trend *P*-value 0.03).

In the multivariate analysis, the main contributory factor of the AE, its nature and if it was reported by a nurse explained if it was avoidable or not. AE due to diagnostic errors, management problems, miscommunication or care given aspects were more preventable than those which were an adverse drug reaction or a medication error. The AE related to care were less preventable (OR = 0.5; 95% CI 0.2–1.1) than effects of medication. Nurses reported more preventable AE than physicians (OR = 1.9; 95% CI 1.2–2.8).

Table 4 Percentage of preventability by nature of the AE and professional category

Nature of the adverse effects	GP and PT (%)	Nurse (%)	Paediatrician (%)	Total (%)
Related to a procedure	72.2	85.4	100	81.7
Associated with healthcare-related infection	73.1	83.9	–	78.9
Related to care	54.5	68.4	–	64.0
Related to medication	52.2	63.0	52	54.5
Worse clinical course of the underlying disease	71.1	86.7	83.3	75.8
Others	81.0	81.8	100	82.2
Total	59.0	74.4	63.4	64.3
P-value	0.002	0.016	0.14	<0.001

Discussion

Though it is true that the majority of the AE in PC have slight consequences, the majority can be avoided easily. Furthermore, we now know the more serious the AE, the more preventable they are. This study further enhances knowledge of patient safety related to the health care provided by focusing on the AE at the first level of care.

It must not go unnoticed that a large number of patients and professionals are annually affected. Considering the frequency of use of PC services in Spain (the annual figure for visits to a health centre is over seven times per person),[25] we could expect 3 million AE per year (6% of all consultations). This shows that each healthcare provider in PC in Spain could be involved in six AE annually. If we also take into account, according to the data from this study, that 65% of AE are preventable, we can conclude that AE in PC constitutes a genuine public health issue in need of more attention.[26,27] Improving diagnosis, prescription and communication with the patient would improve notably the quality assurance.

This study includes not only consultations on account of illness, but also health promotion consultations, as well as monitoring programmes such as those for healthy children. This may explain the differences in prevalence found in paediatric consultations. Moreover, the frequency of AE found in studies at other levels of care suggests that children are less subject to AE than adults.[28]

Risk factors in patients experiencing AE show that the burden of illness in PC is considerable and, if we take into account the fact that some studies have detected a relationship between comorbidity and AE,[24] the results of this study support to some extent the protective role of PC in a National Health Service model.

The most common AE was worsening of the clinical course of the underlying disease, which may derive from a delay in diagnosis or treatment. The pattern of the nature of AE is, therefore, characteristic of the healthcare level. Those AE involving medication effects, also among the most frequently identified, are particularly significant on account of their preventability; as Woods *et al.*[28] note, '22.4% of the drug-induced AE could have been prevented through appropriate follow-up'. Individually, the AE most often found in all studies are associated with prescription, with figures close to 40%.[7] Of these, up to 20% of cases could be considered preventable.[8] Diagnosis-related problems are also considered to be a significant source of AE. Among them, diagnostic error is the most common.[9]

As regards contributory factors, in accordance with other studies,[12] improving communication skills can be seen as a highly positive step, especially considering that poor communication was involved in one in four cases. Errors in identifying patients or scheduling should be minimized as computerized models of care are increasingly assimilated.

Patterns of severity and preventability and the explanatory factors involved seem to be consistent with the care provided in PC. It should be noted, as mentioned elsewhere,[28] that the preventability of AE appears to be independent of their severity.

The design of preventive strategies for avoiding AE in PC is highly effective. An awareness of the magnitude and impact of AE is the first

step in the development of preventive strategies and, consequently, in initiating the cultural change necessary for achieving safer healthcare.

Given the outstanding role medications play both in the origins as well as the consequences of AE, it seems necessary to set out recommendations on the further enhancement of the training of professionals in the proper handling of medications, to standardize the presentation of the information on the medications from the industry to the professionals and from the professionals to the patients so as to provide for their safe use. Improvements in communicating/informing patients in order to better their adherence seems to be a pressing need for improving the safety of the health care provided.

On interpreting these results, consideration must be given to the characteristics of the individuals under study: patients who visit healthcare centres for a medical consultation are necessarily less vulnerable than those involved in other, more intervention-related scenarios.

The review of medical records did not seem an appropriate strategy for assessing the frequency of AE in PC, given the intermittent nature of patient care and the fact that the medical record does not reflect neatly defined individual episodes (as hospital records do), but rather integrated care. Therefore, it was decided to carry out a point prevalence survey, based not on the review of records but on diagnosis in the consultation. This reporting method and the fact that the professional participating in the study was generally the person responsible for the occurrence of the AE may have led to an underestimation of prevalence. Value judgements about preventability could also be affected by this.

PCPs were asked to assess which contributory factors were involved in the production of the AE, but there is a lack of consensus on what constitutes an error.[29] The training sessions also focused on the definitions of AE and contributory factors, and the APEAS form was rated in terms of construct validity.

Reliability on causality and preventability judgements was not analysed. However, knowing how to perform these assessments was strongly emphasized in the training of trainers' workshop. The trainers were provided with the same educational material used in the workshop and with a procedural manual in which some cases were discussed.

In spite of these data probably representing the tip of the iceberg, a large number of patients and professionals suffer their consequences each year. Additionally, AE involves an unnecessary cost and a gap in the quality of the health system due to their consequences. An awareness of the magnitude and impact of AE is the first step on the road to the cultural change necessary for achieving safer healthcare. This study highlights that preventing AE in PC is seen as a top-priority strategy.

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Key points

- An AE could occur in 6% of all consultations in PC in Spain.
- One quarter of AE required no additional care, one quarter required referral to specialist services and the other half were directly resolved at the PC level.
- The more serious the AE, the more preventable they are.
- This study reveals the safeguarding role of the personnel who are the first ones with whom patients come into contact for care.

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Dutch digital breast cancer screening: implications for breast cancer care

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Background: In comparison to other European population-based breast cancer screening programmes, the Dutch programme has a low referral rate, similar breast cancer detection and a high breast cancer mortality reduction. The referral rate in the Netherlands has increased over time and is expected to rise further, mainly following nationwide introduction of digital mammography, completed in 2010. This study explores the consequences of the introduction of digital mammography on the balance between referral rate, detection of breast cancer, diagnostic work-up and associated costs. **Methods:** Detailed information on diagnostic work-up (chart review) was obtained from referred women (*n* = 988) in 2000–06 (100% analogue mammography) and 2007 (75% digital mammography) in Nijmegen, the Netherlands. **Results:** The average referral rate increased from 15 (2000–06) to 34 (2007) per 1000 women screened. The number of breast cancers detected increased from 5.5 to 7.8 per 1000 screens, whereas the positive predictive value fell from 37% to 23%. A sharp rise in diagnostic work-up procedures and total diagnostic costs was seen. On the other hand, costs of a single work-up slightly decreased, as less surgical biopsies were performed. **Conclusion:** Our study shows that a low referral rate in combination with the introduction of digital mammography affects the balance between referral rate and detection rate and can substantially influence breast cancer care and associated costs. Referral rates in the Netherlands are now more comparable to other countries. This effect is therefore of value in countries where implementation of digital breast cancer screening has just started or is still under discussion.

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Introduction

In the last decades, several European countries have implemented a population-based mammography screening programme for breast cancer.[1] Early detection of breast cancer through mammographic screening combined with adequate treatment is at present the most effective strategy for reducing mortality from this disease.[2–4] With 14 553 new cases and 3357 deaths in 2008,[5,6] breast cancer is the most common cancer in women in the Netherlands. The Dutch screening programme has played an important role in the reduction of breast cancer mortality with a 28.7% reduction in 2007 compared to the starting point in 1986–88.[7]

There is a substantial variation in performance measures among individual breast cancer screening programmes in European countries and those in the USA.[1,8–10] The referral rate in the Netherlands is still among the lowest in Europe but slowly reaching the European - average.[1,8–10] In contrast, the number of breast cancers detected is comparable[10] and the breast cancer mortality reduction is among the highest.[9,11]

The referral rate is one of the standard performance measures and is defined as the percentage of screening mammograms that requires women to undergo further diagnostic work-up.[1,10] A too low referral rate will potentially result in late detected cancers.[10,12] An adverse consequence of a too high referral rate is the large number of women with a false positive mammogram. This results in unnecessary diagnostic imaging, extra cost and potentially fear and anxiety.[8,13,14]

A study by Otten *et al.*[12] in Nijmegen determined the effect of referral rate on the detection of breast cancer. Results of this study confirmed that more breast cancers could be detected by lowering the threshold of referral for more subtle mammographic abnormalities. Consequently, given that preliminary findings of the study by Otten *et al.* became available early 2000, the National Expert and Training Centre for Breast Cancer Screening (NETCB) recommended raising the referral rate from 9 to 20 per 1000. Since then, we have already observed a nationwide increase in referrals from 9 per 1000 screened women in the year 2000 to 18 per 1000 in 2007.[7] This change in policy has already resulted in approximately 8000 additional referrals per year.[7,12]

An additional factor that has influenced the referral rate over and above the recommended increase by the NETCB has been the introduction of digital mammography in the screening programme, completed in 2010. Digital mammography allows the image to be manipulated and increases the contrast in dense areas of the breast.[15] Other advantages are a better (early) cancer detection, computer-aided diagnosis and an improvement in workflow.[16] One of the Dutch pilot studies that reported on the consequences of the transition from film-screen mammography to digital mammography showed an increased in referrals from 13 to 22 per 1000.[17]

The aim of this study is to determine the effects of the introduction of digital mammography and, consequently, the effects of the changing referral pattern on the number, type and costs of diagnostic hospital procedures for women diagnosed with breast cancer and women