APEAS STUDY

PATIENT SAFETY IN PRIMARY HEALTHCARE

SUMMARY

GOBIERNO
DE ESPAÑA

MINISTERIO
DE SANIDAD
Y CONSUMO

Plan de Calidad
para el Sistema Nacional
de Salud

This study has been conducted through an arrangement between the Miguel Hernández University and the Ministry of Health and Consumer Affairs

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PROJECT SUMMARY

1. Introduction

One of the key aspects of providing quality healthcare is to ensure that the treatment and care given to patients imply no harm, lesion or complication other than those deriving from the natural progression of their disease and which may be necessary and justified for appropriate diagnostic, therapeutic or palliative handling of the disease.

Healthcare implies risks both for patients and for the professionals caring for them. As diagnostic and therapeutic techniques become more sophisticated, these risks naturally increase. In addition, primary healthcare, which represents a patient's first contact with the healthcare system, is the most visited level of healthcare (and Spain has the highest rates of primary care visits in Europe). Accordingly there are occasions, fortunately highly controlled situations, in which a patient may suffer lesions or complications, without there necessarily being any error on the part of the healthcare professionals involved.

In technical terms, these situations are classed as adverse events (AEs), that is, unforeseen and unexpected accidents that result in harm or complications for the patient and that are a direct consequence of the healthcare received rather than of the patient's disease or complaint. Many of these adverse events are unavoidable, despite the best efforts of the healthcare professionals, but others could be prevented, for example with prior reflection on how to apply certain procedures (catheterisation, administration of drugs, etc.). It is for this reason that the health authorities are promoting programmes aimed at raising clinical safety levels for patients.

An initial study, conducted two years ago and funded by the Spanish National Health Service Quality Agency, analysed the frequency and nature of these adverse events in hospital patients. The ENEAS study[1] was one of the most extensive of its kind worldwide and had a huge repercussion, both within Spain and internationally.

This second study analyses the frequency and nature of adverse events in Primary Healthcare. It is one of the first studies of adverse events to be conducted at the primary healthcare level and covers a wide range of patient visits to medical and nursing services.

The study has been conducted in 48 health centres in 16 Spanish regions, with the voluntary and altruistic participation of 452 nursing and medical professionals. The data analysed correspond to a total of 96,047 patient visits.

2. Objectives

General objectives:

1.- Improve knowledge of patient safety, assessing the magnitude, importance and impact of AEs and analysing the patient and patient care characteristics associated with the appearance of preventable AEs.

2.- Increase the number of healthcare professionals committed to patient safety.

3.- Place patient safety improvement aims and activities on Primary Healthcare teams' agendas.

Specific objectives:

1.- Identify all patient safety incidents deriving from primary healthcare, including near misses (no harm caused to patients) and adverse events (harm caused to patients).

2.- Estimate the frequency of healthcare-related adverse events in health centres in the different Spanish regions.

3.- Identify patient and patient care characteristics in the case of healthcare-related AEs.

4.- Estimate the impact of healthcare in AEs, distinguishing between adverse events which are preventable and those which are not.

5.- Describe the different types of healthcare-related AEs.

6.- Analyse the factors contributing to the emergence of AEs.

7.- Identify the barriers for patient safety among primary healthcare professionals.

8.- Identify the most important AEs, to enable preventive strategies to be designed to reduce them to a minimum.

3. Hypothesis

There are very few studies on AEs in primary healthcare, and those that do exist are concerned with only part of the story as they focus on the error rather than on the adverse event itself, which may be the result of an error and/or of a system failure; after a systematic review[2,3] of the scientific literature, we have found no epidemiological study *sensu stricto*.

Following a pilot study, our working hypothesis is that patient safety incidents may affect at least 3% of all primary healthcare patients and that at least 40% of these incidents may be prevented[4].

4. Methodology

Subjects of study: all patients seen, for any reason, by the primary healthcare teams in the health centres selected.

Design: cross-section observational study with analytical components[5].

Scope of study: 48 primary healthcare centres in 16 Spanish regions.

Sample. Random and voluntary, comprising 452 healthcare professionals (251 GPs, 49 paediatricians and 152 nurses). The health centres were chosen through Patient Safety experts in the regions, scientific societies and key informants.

Result variables: patient safety incidents (near misses and AEs) and preventable AEs.

Determinations: frequency of AEs and proportion of preventable AEs.

Procedure: completion of a form to this effect by the healthcare professionals each time an AE was identified (confidentiality was guaranteed by a concealed identity reporting system).

Data analysis. Description of variables using the statistical methods most suitable to their nature, type and scale. Percentage analysis for qualitative variables; centralisation and dispersion measurements, as appropriate, for quantitative variables. For the bivariable analysis, the χ^2 test or Fisher's exact test was used for qualitative variables and the Mann-Whitney U or t-Student test for quantitative variables (according to whether or not normality criteria were met), as well as variance analysis for comparison of several measurements, considering values of $p < 0.05$ to be significant. Logistic regression was used to analyse the association between variables.

5. Results

During the study period, 96,047 patient visits were recorded at the primary healthcare centres and 452 healthcare professionals identified 2,059 alerts corresponding to 1,932 patient visits. Of these patient visits, 63.5% were handled by GPs, 26.5% by nurses and 10.0% by paediatricians.

Prevalence rate of patient safety incidents: 18.63‰ (CI95%: 17.78–19.49). Prevalence rate of near misses: 7.45‰ (CI95%: 6.91–8.00). Prevalence rate of adverse events (AEs): 11.18‰ (CI95%: 10.52– 11.85). Prevalence rate of patients with an AE: 10.11‰ (CI95%: 9.48–10.74). Percentage of patients with more than one AE: 6.7%.

Severity of AEs: 54.7% (n=606) were considered minor, 38.0% (n=421) moderately serious and 7.3% (n=81) serious.

Women accounted for 57.4% of the total. The median age was 59, and the mean age was 53 for both sexes. 58.0% of those affected by AEs presented one or more risk factors.

We note that in 48.2% of cases the causal factors of the AEs were connected with medication, in 25.7% they were care-related, in 24.6% they were associated with communication, in 13.1% with the diagnosis, in 8.9% with handling and in 14.4% with other causes.

Considering the consequences (effect) of the adverse events, we note that 47.8% (530) of the AEs were connected with medication and that care-related (nosocomial) infections represented 8.4% (93) of the total, while 10.6% (118) were associated with procedures and 6.5% (72) were care-related.

The most frequent adverse events were nausea, vomiting or diarrhoea as a side effect of medication, skin rash or lesions as a reaction to drugs or dressings, infection of surgical and/or traumatic wounds and neurological disorders as a side effect of drugs. In total, these accounted for 44% of all adverse events.

Of the AEs identified, 6.7% (n=74) were considered totally unavoidable, 23.1% (n=256) difficult to prevent and 70.2% (n=778) clearly preventable.

In terms of preventability relative to their degree of severity, 65.3% of minor AEs, 75.3% of moderately serious AEs and 80.2% of serious AEs were preventable. This is a statistically significant difference (value of $p < 0.001$).

In 23.6% of cases the consequences of the AEs had no effect on health care, whilst in 33.1% they implied a higher level of observation and monitoring, in 7.5% they implied the need for further tests and in 17.1% additional surgical or medical treatment was provided at the primary healthcare level. In 24.9% of cases the consequences of the AEs implied a need for consultation or referral to specialist care (without hospital admission) and in 5.8% they implied a need for life-saving hospitalisation.

6. Conclusions

These results show that primary healthcare is reasonably safe healthcare: there is a low rate of occurrence of adverse events, and most of those that do occur are minor.

Nevertheless, patient safety is important at the primary care level, as although the rate of occurrence of AEs is relatively low, the high number of patients visiting these healthcare centres means that the absolute number of patients affected is significant. If we were to extrapolate the results to the population as a whole, an average of seven persons out of every 100 could be affected in one year.

Prevention of adverse events at the primary healthcare level should therefore be a priority strategy, given that 70% of all adverse events, and 80% of all serious adverse events, are preventable. Accordingly, despite the good results obtained from this study, these figures should herald a move towards raising clinical safety levels.

There are a multitude of causes of adverse events, including factors connected with the use of drugs, communication, handling and care practices.

In most cases, an adverse event will have a negative impact on the evolution of the patient's original disease or complaint; moreover, the number of cases of care-related (nosocomial) infections at primary healthcare level cannot be deemed insignificant.

In our study one quarter of all AEs required no additional care and one quarter required referral to specialist services, while the other half were resolved directly at the primary healthcare level.

7. VALUE OF STUDY

7.1.- Contributions to knowledge base:

The APEAS study contributes a methodology for analysis of adverse events at the level of primary healthcare.

It is a benchmark, as it is the first epidemiological study with such a large patient sample (96,047 patient visits). It represents a diagnosis of the situation in the Spanish healthcare system and opens up a line of research that will result in important benefits for patients.

The variety of causes responsible for adverse events means that a multifactor approach must be used to effectively improve Patient Safety.

The study demonstrates the protection provided by healthcare personnel at the patients' first point of contact with the healthcare system.

7.2.- Contributions to clinical practice:

Given the importance of drugs in both the origin and consequences of adverse events, the form of presentation of information on medication, by the industry to healthcare professionals and by these latter to patients, should be standardised, even in the IT applications associated with clinical records, to ensure safe use of all medication. This is an urgent requirement.

Procedures and care practices must be continuously updated, to incorporate the latest and safest techniques available thanks to scientific progress.

The introduction of strategies to improve patient safety at the level of primary healthcare is extremely effective, considering that 70% of all adverse events and 80% of all serious adverse events are preventable.

8. FINAL REFLECTION

This study has been possible thanks to the collaboration of primary healthcare professionals throughout the country. The sample is not significant in terms of size, but it is significant in terms of their qualifications, their numbers and their desire to improve the provision of healthcare in Spain.

The frequency of adverse events in primary healthcare should be at least equal to that identified in this study, and should be expected to rise in coming years, but the health system's commitment and the motivation of its professionals should mitigate this effect.

9. NOTES

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