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**Servicio Navarro de Salud / Osasunbidea**
Plaza de la Paz, s/n - 31002 Pamplona
**T** 848429047 - **F** 848429010
farmacia.atprimaria@cfnavarra.es

summary

**Objetive.** To outline the importance of medication errors and offer helpful tools to reduce their incidence. **Methods.** Research on information related to the topic from the main patient safety agencies. Research on systematic reviews evaluating medication errors especially in primary care was also made in the main data bases on evidence-based medicine. Two clinical cases have been employed to illustrate errors in medication and the possible measures to avoid their recurrence. **Results and conclusions.** Patient safety has become a priority worldwide and medication errors represent an important percentage of preventible adverse effects related to health systems. Although the incidence of errors in medication is low, the great number of patients attended to increases the number of patients affected. Diverse tools have been developed to detect errors, investigate and learn from them and to establish corrective measures. There are different elements that should be taken into account to improve safety.

# Patient safety, beware of medication errors!

JAVIER GARJÓN
Drug Prescribing Service. SNS-O

JAVIER GORRICHO
Drug Prescribing Service. SNS-O

**The two clinical cases that follow serve to illustrate the nature of the content of the article. At the end of the paper an evaluation and a proposal of some measures regarding these cases is made so that such errors do not occur again.**

## CASE 1
## Accidental overdose of intravenous paracetamol (acetaminophen, USA) in pediatrics

*(Based on a real case)*

In a pediatric surgical unit, a pediatrician prescribed the following for a 7-week old baby weighing 2 kg after inguinal hernia surgery: Paracetamol i.v. 19.5 every 6 hours.

The nurse administered 19.5 ml of Perfalgan® (paracetamol) 10 mg/mL with a total dose of 195 mg of paracetamol equivalent to 74 mg/kg, a 10-fold overdose.

The error was detected by another nurse after the second dose was administered. Then plasmatic levels of paracetamol were determined and the antidote N-acetylcysteine was given. Liver function remained unaffected. Vitamin K was administered to correct an altered INR. After 5 days the patient was discharged with no secuelae.

## CASE 2
## Adverse reaction to cilostazol due to a possible interaction with a proton pump inhibitor

*(A fictitious case based on different detected errors)*

A 55 year old patient called on the emergency department complaining of right knee pain. After evaluation, the patient was prescribed 50 mg diclofenac three times a day and 20 mg omeprazole once daily and follow up by his physician was indicated. After successive appointments with his family doctor, the patient referred improvement and diclofenac was discontinued.

Some time later, he complained of pain in the left leg after walking a distance of 40 metres which was relieved by rest. Palpation of pedial pulses was weak. The patient was referred to the emergency department where he was diagnosed of intermittent claudication and was prescribed triflusal 300 mg twice daily, amiloride-hydroclortiazide 5/50 mg once a day, pentoxifylline 400 mg twice daily and cilostazol 100 mg twice daily.

After three days, the patient was seen at his primary care centre for tachycardia, and eventually diagnosed with atrial fibrillation.

## Introduction

Patient safety has become an important priority in health systems throughout the world, especially because different epidemiological studies have brought to light that the same health care destined to improve the health of people is also an important source of harm, where medication errors is one of the main causes of preventable harm[1,2]. Interest in this field has raised through different initiatives such as the striking publication of the report "To Err is Human" by the Institute of Medicine in the USA[3], or the creation of the World Alliance for Patient Safety by the World Health Organization (WHO)[4].

Different models have been proposed by health systems as a whole including more or less global measures at primary care or specialized levels. On evaluating the possible application in other contexts, the particular characteristics of the region should be taken into account.

A clear example of a global programme for the improvement of patient safety is the guideline: "Seven steps to patient safety for primary care" by the National Patient Safety Agency of the National Health Service in the United Kingdom, which was translated into Spanish by the Quality Agency of the National Health Service of Spain[5]. The guidelines endeavour to create a "new culture" and draw attention to the problem and attempts to find solutions. It advocates for open communication, the need to listen to patients, notification of incidences both at local and national levels, the use of root cause analysis and the obligation to implement solutions.

Patient safety improvement is one of the areas for action of the Quality Plan for the National Health Service of Spain[6]. This improvement is incorporated in the denominated the "Strategy #8" whose objectives with respect to medication errors are:
· Promote and develop knowledge and a safety culture among professionals at all levels of health care.
· Design and establish systems to allow for the communication of incidents related to patient safety.
· Implement projects through agreements with all the self governing provinces that promote and evaluate safe practice in eight specific areas. One of these includes the prevention of medication errors.

The Department of Health of the Government of Navarre has taken on the responsibility to promote excellence in heath care and strategies that promote patient safety. The strategic directions are oriented primarily towards the following:
· Develop a culture of safety among health professionals.
· Promote the development of effective clinical practices in prevention and assuring a minimum of adverse effects.
· Promote investigation in areas related to excellence in health care and patient safety.

## What are we talking about?

When a person receives a prescription, one expects to receive beneficial effects and assumes the risks incurred. Thus, **drug related adverse effects** are defined as "any injury due to medication". These risks are mainly of two types[2]:

**Inevitable.** Adverse drug reactions are those known adverse effects of medication that cannot be prevented even though adequate measures are taken to avoid them.

**Evitable.** These are medication errors which are those preventable events that may cause or lead to an inappropriate medication use or patient harm.

In this article we will focus on medication errors, with the intention to describe them, evaluate their importance in our context and explain what the most adequate tools are to reduce their incidence.

## The magnitude of the problem

In two recent studies, an analysis was made of the adverse effects (AE) related to health care in Spain, ENEAS[7] in hospitals (with collaboration from the Hospital de Navarra) and APEAS[8] in primary care centres (collaboration from Iturrrama and San Jorge primary care centers). In both transversal studies the incidence of adverse effects notified by health care professionals in selected samples of those who agreed to participate in the study was evaluated.

In the ENEAS study, 4% of reviewed patients suffered from at least one adverse effect related to medication. Of these episodes, more than 30% could have been avoided.

In the APEAS study a 1% prevalence of adverse effects was observed and 48% of them were related to medication. Of these episodes, a little over half of them were due to errors while a little less due to adverse reactions to medication.

All this shows that health care offered at primary care is reasonably safe: the frequency of AE is low and mostly mild. Despite the relatively low rate of AE, the high rate of consultancies in primary care in Spain leads to a numerous amount of patients affected in absolute terms. When applying the results to the general population, an average of 7 per 100 persons could be affected annually. Of these, half would be affected by medication errors.

The application of the results obtained in these studies to Navarre shows that, in one year, 700 cases in hospitals and 640 cases in primary care could have suffered from adverse effects caused by medication errors with moderate or severe consequences. Multiple causes present in the origin of AE demand for a multifactorial approach to effectively improve patient safety. The elaboration of preventive strategies is highly effective, as an elevated percentage of adverse effects can be avoided.

**Table 1.** Epidemiological studies on patient safety.

| | |
|---|---|
| **ENEAS** | |
| 24 hospitals | 5,624 patients |
| Subjects under study | Patients admitted for more than 24 hours and discharged between June 4th to 10th, 2005. |
| Incidence adverse effects (AE) (% patients) | 9.3% (95%CI 8.65 – 10.1%) |
| Incidence medication related AE (% patients) | 4.0% |
| % medication related AE / total AE | 37.4% |
| % medication related AE which are avoidable | 34.8% |
| % of medication related AE that require hospital re-admission | 29.8% |
| **APEAS** | |
| 48 primary care centres | 96,047 consultancies (63.5% of the registered consultancies were attended to by family doctors, 26.5% by nurses and 10% by pediatricians) |
| Subjects under study | Patients that came to the consultancy in the two interim weeks of June 2007. |
| Prevalence of AE (% patients) | 1.01% (95%CI, 0.96% - 1.07%) |
| % Medication related / total AE | 47.8% |
| Severity* of medication related AE | Mild: 64.3% Moderate: 30.0% Severe: 5.7% |
| % medication related AE which are avoidable | 59.1% |
| % moderate and severe medication related AE that are avoidable | 66.1% |
| % severe medication related AE | 37.0% |

(*) **Severe:** may cause death, residual discapacity on discharge or require surgery. **Moderate:** may require hospital admission of at least one day, attention at the emergency department or specialist consultancy. **Mild:** none of the above.

## How can we detect the problem?

As commented, once a culture for safety has been created, it is important to detect medication errors. The most frequent methods employed include: voluntary notification, direct observation, revision of clinical records and the critical incident technique.

### Voluntary reporting

This is the most recommended approach to initiate a program for the detection of medication errors and one of the first measures to be implemented in the health services of different countries. It is based on the voluntary reporting of medication errors that may occur in daily clinical practice by health professionals or the patients themselves.

It should be taken into account that, in Spain, since 2007 reporting of medication errors should be made after their inclusion in the definition of adverse reaction[9]. Thus, in the recommendations that appear at the website of the Spanish Medicines Agency[10] it is specified that adverse reactions originating from medication errors should be notified. Priority is given to severe reactions and those reactions involving new drugs (less than 5 years on the market). A national system for notification and registry of incidents and adverse events will be set up[11].

This method is easy to introduce, improves the culture for quality among health professionals and the safety of patients by detecting critical points that have failed and taking the necessary corrective measures.

The main problem is that the person reporting the incident may have a feelings of guilt or fear that the "error is discovered". However what is more important to understand is that **what fails is not so much the person but rather the systems**. Of course, this does not mean that individuals can be careless. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

### Direct observation

Work carried out by a health professional is supervised by another professional. This has been done in hospitals. This method detects the most errors, but involves a high consumption of resources. It has been employed mainly to investigate the prevalence of medication errors within a specific context.

### Revision of clinical records

Clinical medical records are reviewed to find possible errors related to medication. More errors are detected than by voluntary reporting, but less than by direct observation. This method bears more weight on resources than voluntary reporting. Both the ENEAS and APEAS studies are an example where this method is employed.

### Critical incidents technique

This consists of the reporting and analysis of critical events, including incidents that could produce injuries or death. Measures are extracted from their analysis in order to avoid future errors. Problems with this method are similar to those with voluntary notification.

## Which drugs bear the most risk?

The so-called "high alert medications" refer to those drugs that possess a very high "risk" of causing serious harm or even death when errors occur with their use.

This definition does not mean that the errors related to these medications are the most frequent, but rather if an error did occur, the consequences for patients would be usually more severe. For this reason, high alert medications are a priority in all clinical safety programs established in hospitals[12].

The Institute for Safe Medication Practices[13] has elaborated a list of high risk medications for hospitals, some of which are employed in primary care.

### In primary care patients

Studies on preventable adverse effects in primary care frequently include those medications that cause the need for hospital admission[14,15,16]. The most frequent pharmacological classes involved include: antiaggregant agents, diuretics, NSAIDs, anticoagulants, opioids, betablockers, ACE inhibitors / ARBs, antidiabetic agents, digitalis, corticoids, antidepressants, calcium channel blockers, antiepileptic agents, nitrates, antiasthmatic agents.

Besides the risk of each group, this list could also reflect the volume of prescriptions and the feasibility to attribute problems with medication use.

**Table 2.** High alert medications.

| CLASS/CATEGORIES OF MEDICATIONS | |
|---|---|
| Radiocontrast agents IV | Epidural or intrathecal medications |
| Inotropic agents IV (ej. digoxin, milrinone) | Medications with conventional and liposomal presentations (eg. anphotericin B) |
| Adrenergic agonists IV (adrenaline, dopamine, L-noradrenaline) | Opioids IV, transdermal and oral (all presentations) |
| Anesthetic agents, general, inhaled and IV (eg. ketamine, propofol) | Moderate sedative agents IV (eg. midazolam) |
| Adrenergic antagonists IV (eg. esmolol, labetalol, propranolol) | Moderate oral sedative agents for children (eg.chloral hydrate) |
| Antithrombotic agents IV (eg. abciximab, eptifibetide, tirofiban) | Cardioplegic solutions |
| Antiarrhythmics IV (eg. amiodarone, lidocaine) | Hypertonic glucose solutions (≥ 20%) |
| Oral anticoagulants (eg. acenocumarol) | Dialysis agents (peritoneal and haemodialysis). |
| Oral antidiabetics (ej. glibenclamide) | Solutions for parenteral nutrition |
| Neuromuscular blockers (ej. suxametonium, rocuronium, vecuronium) | Thrombolytics (eg. alteplase, alpha-drotrecogin , tenecteplase) |
| Cytostatic agents (oral, IV) | |
| Heparin and other antithrombotic agents (eg., antithrombin III, enoxaparin, heparin, fondaparinux, lepirudin) | |
| **SPECIFIC MEDICATIONS** | |
| Sterile water for injection, inhalation and irrigation in containers ≥ 100 mL (excluding bottles) | Insulin SC and IV |
| Potassium chloride for injection IV (concentrated solution). | Metotrexate oral (Non oncologic use) |
| Hypertonic sodium chloride (≥0.9%) | Sodium nitroprusside IV |
| Epoprostenol IV | Oxytocin IV |
| Phosphate potassium IV | Promethazine IV |
| | Magnesium sulphate IV |

## Factors that increase safety in medication use[6,12,17,18]

### Leadership

The organization should develop a culture of safety and the managers should lead in promoting a clear, solid and maintained policy among all personnel. It should not be a question raised by enthusiasts, research fellows, or pestering individuals.

### Conciliation of treatment

A single patient may interact with various doctors at different levels of assistance and each doctor may treat different health problems affecting the patient. If each physician prescribes without a global vision, problems will arise as a result of unnecessary polymedication, duplicities, interactions and the use of contraindicated drugs given the patient's situation.

To conciliate implies the consideration of all the medication a patient is taking. Each prescription should be judged with regard to the rest of the patient's prescriptions and the patient's general situation within a process under continual review. Correct prescription is a responsibility of all health professionals, but is undeniably a central role of the family doctor who receives all the information concerning the patient and who is in a position to form a holistic view of the patient's condition.

**A project of medication review in polymedicated patients in the Primary care management of the Navarre Health Services (SNS-O) :**

**Justification:**
Polymedicated patients present a high risk of adverse reactions, medication errors and inadequate use of medication. A review of all drugs taken is recommended with each new patient, every 6 to 12 months and whenever any change is made to the patient's treatment regimen.

**Method:**
A list of 15 patients who have more than 10 different medications dispensed in the last three months should be sent to each family doctor.
During the year 2010, primary care physicians carried out measures outlined below related to polymedicated patients identified in the list:

**1. Know the characteristics of all the medications the patient is taking and how they are administered.**
Instruct the patient to bring all medications (including over the counter drugs or medicinal plants) at the next appointment.

During the consultancy ask :
If the patient is taking the medication
If the patient knows the indication for taking each medication.
What administration regimen the medications have.
Dose and time of intake.
Duration of treatment.
For any adverse effect experienced by the patient.

**2. Identify each medication by its active substance (reduces confusion in commercial names and helps identify (duplicities in treatment).**

**3. Identify the clinical indication for each medication.**

**4. For each drug received by the patient, the doctor should consider the following questions and act accordingly:**

Is the original indication for which the drug was prescribed still present?

Is there evidence of the efficacy of the drug with regard to the indication for which it was prescribed?

Is the drug proving effective given the management goals set for the patient?
Withdraw all medications with no clinical indication or no therapeutic benefit

Are there duplicities in pharmacological treatment?
Is there a possibility to simplify treatment?
Withdraw duplicated medications, adjusting doses if necessary.

Is there adherence to treatment and is the medication adequate given the characteristics of the patient?
Reconsider the treatments the patient is not taking.
Simplify treatments by making more simple regimens.
Carry out health education on correct use of medications.

Are the right doses administered given the characteristics of the patient?
Adjust the dose.

Has there been any adverse reaction or is there any preventable risk for one to occur?
Consider discontinuing or substituting the drug for a safer agent.
Endeavour not to treat an adverse reaction by employing another drug.
Evaluate the risk for interactions.

Are the required controls for evaluating efficacy and safety of the medication being carried out?
Programme necessary controls.

*Given the complexity of the health system medication errors affect a numerous amount of patients.*

In cases of patients admitted to hospital, conciliation should be periodically carried out at transition points: at admission and during transfers. To do this more reliably, an updated list of medications taken by the patient should be made including over the counter drugs and alternative medicinal products. In addition, standard information of medications should be included when transferring patients and during referrals to other specialties.

In the process of conciliation the patient is asked whether the drug is taken, how it is taken and whether the patient has experienced any adverse effect. Team work with nurses and pharmacists can be of great help when managing treatments.

**EXAMPLE OF GOOD PRACTICE**

**Project for the implementation of a conciliation programme for pharmacological treatments at the Hospital Virgen del Camino**

**Design and implementation of standard procedures for conciliation of medication during transfers at two levels: admission and hospital discharge.**

· Elaboration of an evaluation report regarding the implementation of the procedure. It is necessary to constantly carry out a quantitative evaluation of the effects of different interventions that are carried out to improve the safety of the patient. This allows for an evaluation of the impact and continued improvements derived from the measures implemented.

· Report on the conditioning factors and barriers to the implementation of the desired measures.

**Implementation of a conciliation circuit for medication taken by all patients admitted to the hospital.**

1. Assign personnel responsible for conciliation of medications: an initial evaluation by the physician and the nurse in charge of the patient and a pharmacist responsible for the conciliation of the medication within a pre-established period.
2. Review of the clinical information generated by the current episode.
3. Retrieval of the pharmaceutical history of the patient by reviewing the clinical records. Primary care and/or resident home reports, previous medical reports from earlier admissions, and an interview with the patient and/or family.
4. Design of a standard form to record the list of current medication.
5. Conciliation of treatments: examination of discrepancies between the previous list of medications and the new medication orders.
6. Pharmacological and treatment orientation and follow up.
7. Provide access to information regarding medications and advice from the pharmacologist at each step of the conciliation process.

**Implementation of conciliation in Primary Care after hospital discharge.**

· Procedure after hospital discharge: along with the medical and nurse report and prescriptions at discharge, information on the medication received is provided using the computer-based programme, Infowin®.

· The aim is to inform the patients on their medication at discharge and to ensure that professionals involved in the conciliation process at Primary Care level have also access to this information.

**Classification of discrepancies:**

We differentiate those that require clarification from those that do not.

**Justified discrepancies that do not require clarification:**

· Medical decisions to discontinue medication or modify doses, frequency or administration route given the current clinical situation of the patient.

· Initiation of new medication given the clinical situation of the patient.

· Medical decisions to modify posology or route of administration of a drug given the new clinical situation of the patient.

· Therapeutic substitutions according to the hospital formulary issued by the hospital and medication exchange programmes.

**Discrepancies not justified that require clarification:**

· Omission of the necessary medication.

· Addition of unjustified medication given the clinical situation.

· Different doses, routes of administration, hourly frequency or method of administration, different medication, incomplete prescriptions.

· Medication not available in the pharmacological list of medications of the hospital, duplicities, interactions.

· Discrepancies with no apparent justification should be communicated to the clinical team both personally and by written record.

**For more information please contact:**
Gabriela Elizondo Rivas (Hospital Pharmacist)
Pharmacy Service, Hospital Virgen del Camino.
Tel. 848429454
gelizonr@navarra.es

## Electronic prescription

Helps to standardize treatments and avoids legibility problems. The objective is that electronic based prescriptions include aids to the clinical decision process on medications at different levels[19].

**Basic level:** control of allergies to drugs, a basic guide to dosage, control of duplicities and interactions.

**Advanced level:** aid to adjustments of doses in cases of renal impairment and elderly patients, guide to laboratory controls related to medication, control of medication in pregnancy and contraindications of the drugs according to existing diseases.

In any case, it should be noted that an inadequately designed information system can be an important source of errors.

## Communication

All those implicated in the use of a medication should have access to the information.

Communication skills should be developed and team work fostered to be prepared and gain confidence to question medical prescriptions when an error may occur.

Communication of errors and adverse reactions would be much easier in an open and non-accusing environment. There are communication tools at national and regional levels, but it would also be especially interesting to be able to communicate errors within a team which is where corrective measures would be implemented more efficiently. Perhaps the best lessons come from clinical cases where errors occurred.

## Standardization of work procedures

Working in an orderly fashion, and trying to minimize variability in practice may help reduce the possibility of an error occurring. Some measures include:

· Physical barriers that make errors difficult or impossible to commit (for example, use of special syringes for the administration of oral solutions of drugs that cannot be connected to intravenous routes in order to avoid their administration through an erroneous route).

· To limit the number of options only to those strictly necessary: limit the number of medications in the formularies so as to create greater familiarity with them. In addition limitations can be made on the number of concentrations and volumes of certain agents.

*What fails is not so much the people involved, but rather the systems.*

· Identification and review at least annually the list of medications for agents with similar sounding names and measures to prevent errors with these drugs. Avoidance of abbreviations.

· Centralize the processes where it is most likely to commit errors. One of the processes that is most convenient to centralize in the hospital pharmacy is the mixture of high risk intravenous agents.

· Maintain safe working environments to prepare medications, their administration and documentation: for example adequate illumination.

· Use protocols and report templates. Register the age and weight of the patient.

**EXAMPLE OF GOOD PRACTICE:**
**Website for the Safe use of medication and Health products of the Province of Madrid**
**https://www.seguridadmedicamento.sanidadmadrid.org/**

· Notifications of errors in medication, suspicious adverse drug reactions, incidents with health products and other information related to drug safety are all integrated at one website.
· Notifications of adverse drug reactions in the yellow card format and medication errors, with adapted forms for Primary and Specialized Care.
· Notifications of errors are channeled through the Functional Units of Risk Management, multidisciplinary units present in primary care health areas and in all hospitals.

*A culture for safety should be developed, both in the health system and among patients.*

Observatorio Regional de Riesgos Sanitarios

## SEGURIDAD DE MEDICAMENTOS EN LA COMUNIDAD DE MADRID

SaludMadrid Comunidad de Madrid

**Nº NOTIFICACIÓN**

**REALICE UNA BREVE DESCRIPCIÓN DEL INCIDENTE: SECUENCIAS, CARACTERÍSTICAS, CONSECUENCIAS… QUE PUEDA COMPLEMENTAR LA INFORMACIÓN RECOGIDA EN LOS APARTADOS ANTERIORES**

**DESCRIPCIÓN DE MEDIDAS QUE SE ACONSEJAN PARA EVITAR ESTE ERROR**

*Los datos de carácter personal recogidos en este formulario serán incorporados y tratados en el fichero manual estructurado de Seguridad de Medicamentos y en la base de datos de Seguridad de Medicamentos de la Consejería, inscritos en la Agencia de Protección de Datos de la Comunidad de Madrid . La finalidad de estas notificaciones es detectar incidentes ocurridos con los medicamentos con el objetivo de subsanarlos y evitar estos incidentes en el futuro. Las notificaciones serán remitidas a la Dirección General de Farmacia y Productos Sanitarios de la Comunidad de Madrid en razón de sus competencias, en donde se podrán ejercer los derechos de acceso, rectificación, cancelación y oposición ante el mismo.*

Observatorio Regional de Riesgos Sanitarios

## SEGURIDAD DE MEDICAMENTOS EN LA COMUNIDAD DE MADRID

## Seguimiento en ATENCIÓN PRIMARIA

SaludMadrid Comunidad de Madrid

Por favor, notifique todos los errores de medicación que puedan producirse en la utilización de medicamentos. **Esta información es CONFIDENCIAL.**

| Nº NOTIFICACIÓN | NOTIFICADOR | FECHA INCIDENTE | TURNO | ¿FUÉ LA MEDICACIÓN ADMINISTRADA? |
|---|---|---|---|---|
| | Tfno: | / / | ☐ Habitual ☐ Urgencias | ☐ Sí ☐ No ☐ Se desconoce |

**SELECCIONAR EL TIPO DE ERROR QUE MEJOR SE AJUSTA AL EVENTO (SÓLO 1)**

- ☐ Selección inapropiada del medicamento
- ☐ Prescripción y/o utilización de fármacos fuera de indicación
- ☐ Prescripción y/o utilización de fármacos contraindicados en ficha técnica
- ☐ Duplicidad de medicamentos o utilización de fármacos innecesarios
- ☐ Error en la dosis: omisión o incorrecta
- ☐ Frecuencia de administración errónea
- ☐ Forma farmacéutica errónea
- ☐ Error en la preparación/ manipulación/ acondicionamiento
- ☐ Técnica de administración incorrecta
- ☐ Vía de administración incorrecta
- ☐ Paciente equivocado
- ☐ Duración del tratamiento incorrecta
- ☐ Se prescribe un medicamento que no está comercializado
- ☐ Se prescribe un medicamento que no suministran los distribuidores
- ☐ Monitorización insuficiente del tratamiento
- ☐ Medicamento deteriorado: caducado, mal conservado o con defectos en la calidad
- ☐ Falta de cumplimiento del paciente

**SELECCIONAR LA CAUSA QUE MEJOR SE AJUSTA AL ERROR**

- ☐ Problemas en la interpretación de la prescripción: ambigua, ilegible, uso de abreviaturas, unidades de medida no aceptadas internacionalmente…
- ☐ Incorrecta identificación del paciente
- ☐ La presentación de la especialidad farmacéutica da lugar a confusión: nombres similares, similitud de envases, descripción en el cartonaje ó etiquetado incorrecto o equívoco.
- ☐ Problemas en los equipos y dispositivos de dispensación/ preparación/administración
- ☐ Falta de conocimiento/formación
- ☐ Falta cumplimiento procedimientos de trabajo establecidos
- ☐ Defectos en la calidad del medicamento
- ☐ Falta de concordancia entre las bases de datos y los medicamentos comercializados
- ☐ Otros: situación de emergencia, falta de procedimientos normalizados, personal insuficiente o sin experiencia

**SELECCIONAR LA OPCIÓN QUE MEJOR SE AJUSTE A LA EVOLUCIÓN DEL PACIENTE (NO IMPLICA RELACIÓN CAUSAL CON EL ERROR)**

- ☐ A. Circunstancias o eventos con capacidad de causar error
- ☐ B. El error se produjo, pero no alcanzó al paciente
- ☐ C1. El error llega al paciente pero no se administra
- ☐ C2. El fármaco erróneo se administra aunque no se produjo daño
- ☐ D. El paciente requirió monitorización y/o intervención aunque no se produjo daño
- ☐ E. El paciente presentó un daño temporal que requirió intervención médica
- ☐ F. El paciente ha precisado o prolongado la hospitalización
- ☐ G. El paciente presentó un daño permanente
- ☐ H. Se ha requerido intervención para mantener la vida del paciente
- ☐ I. Muerte del paciente
- ☐ X. El error se ha producido, pero no se ha podido hacer seguimiento y conocer el daño

| ETAPA DEL PROCESO | DÓNDE OCURRE | DÓNDE SE DETECTA |
|---|---|---|
| Autorización (Denominación, etiquetado, prospecto, ficha técnica…) | ☐ | |
| Fabricación (Calidad) | ☐ | |
| Suministro por fabricante | ☐ | |
| Prescripción | ☐ | ☐ |
| Dispensación | ☐ | ☐ |
| Administración por prof. sanitarios | ☐ | ☐ |
| Administración por paciente | ☐ | ☐ |
| Comunicación: entre profesionales o desde la Administración | ☐ | ☐ |

**PERSONA QUE LO DETECTA**

- ☐ Farmacéutico
- ☐ Médico
- ☐ Enfermera
- ☐ Auxiliar de enfermería
- ☐ Paciente
- ☐ Familiar
- ☐ Otros: higienistas, estudiantes

**ORDEN DE TRATAMIENTO**

| | |
|---|---|
| Formato | ☐ Prescripción informatizada |
| | ☐ Prescripción manual |
| | ☐ Vacunación/Botiquines |
| Tipo | ☐ Receta oficial |
| | ☐ Informe de urgencias |
| | ☐ Informe de alta |
| | ☐ Informe atención especializada |
| | ☐ Receta blanca |
| | ☐ Vacunación/Botiquines |

**LUGAR DÓNDE SE HA PRODUCIDO**

- ☐ Centro de atención primaria
- ☐ Consulta de centro de especialidades
- ☐ Consulta externa del hospital
- ☐ Otras consultas: entidades colaboradoras, médicos empresa…
- ☐ Domicilio del paciente
- ☐ Urgencias del hospital
- ☐ Urgencias SUMMA
- ☐ Oficina de farmacia
- ☐ Unidad de hospitalización
- ☐ Otros: laboratorio fabricante, residencia de ancianos, servicio farmacia

**APORTA IMAGEN DEL ERROR** ☐ Sí ☐ No

**LOTE Y CADUCIDAD** (SI DEFECTO EN CALIDAD)

**CARACTERÍSTICAS DEL MEDICAMENTO PRESCRITO**

| | |
|---|---|
| Código nacional | |
| Especialidad farmacéutica | |

**CARACTERÍSTICAS DEL OTRO MEDICAMENTO IMPLICADO**

| | |
|---|---|
| Código nacional | |
| Especialidad farmacéutica | |

**CARACTERÍSTICAS DEL PACIENTE**

| | |
|---|---|
| Edad | _____años _____meses |
| Sexo | ☐ Varón ☐ Mujer |
| Nº fármacos | |
| Otros | |

**Remitir a la Unidad Funcional para la Gestión de Riesgos Sanitarios correspondiente**

· Follow clinical guidelines and protocols elaborated on evidence-based medicine.

· When administering medication ensure that five critical points are correct: correct **patient**, correct **medication**, correct **moment and frequency** of administration, correct **dose** and correct **route** of administration.

· Use double checking techniques or independent checking.

· With respect to the identification of patients, administration of medication has been proved safe when employing new technologies, for instance, identification bracelets with bar codes[20]. However, it should be taken into account that even a simple measure such as addressing the patients by their names to ensure that they are the patients that need to receive the medication can play an important role.

### An active attitude towards safety

Health professionals should bear in mind that new problems presented by patients may be due to adverse drug reactions.

They should also be aware of high risk situations that may affect their work: stress, lack of adequate sleep, anger; or supervision of personnel that are not experts.

Before prescribing a drug which one may not be very familiar with, the Summary of Product Characteristics should be consulted. One should be accustomed to consulting rigorous sources of information on medications. In the Pharmacy Departments of hospitals and primary care, drug information services are available. They exist to be used.

### Implication of patients

Patients are the ones who suffer from errors and therefore they and their families should be involved in their prevention. To do so:
· Patients should be informed about the indications and possible adverse effects of the medications they are prescribed.
· They should be encouraged to communicate their concerns about the safety of the drugs to their health professional.
· The implication of the patients and their carers should be facilitated by controlling in checking the administration, and monitoring the effects of drugs wherever and whenever they are prescribed.

## Learning from errors: root cause analysis[21]

Errors repeat themselves and therefore when one occurs it is important to reflect on the factors that may have caused the error in order to take adequate measures.

Root cause analysis (RCA) is a technique employed to carry out a systematic investigation to examine beyond simply those persons involved but rather to search for an understanding of the underlying causes and context where any incident has occurred.

In general there is a chain of events and a great variety of contributing factors that precede an event leading to an error.

The approach is retrospective and multidisciplinary, and is designed to identify the sequence of events, applied in retrospect to the event. This allows for the discovery of the real causes behind an incident, so that the organization can learn and establish corrective measures.

It consists of addressing the following questions: What happened? Why did it happen? What can be done so that it never occurs again?

More information on training materials and tools regarding root cause analysis can be found at the websites provided later on. The different stages of the RCA are described in table 3.

## A practical application of a simplified approach to manage the two cases described in this article (Some aspects that include root cause analysis)

### CASE 1

#### Detected errors

· Medical order incomplete that gives place to ambiguous interpretations (prescription referred to 19.5 mg when 1.95 mL was the correct dose to be administered).
· The ambiguous medical order was not confirmed by the nurse (the nurse interpreted 19.5 mL)
· Administration of a dose far superior to the recommended dose (195 mg was administered).

#### Questions that arise

Are there prescription protocols for this drug in infants?
Is there a protocol for administration of medication in infants?

*Root cause analysis is a useful tool to investigate errors.*

If they do exist, is there compliance to them?
Was the nurse trained to work with infants?
Is there work overload that may increase the risk of errors?
Is there adequate communication between doctors and nurses to resolve doubts and queries?
Is there any computer-based software for prescriptions?
If so, why was it not employed?

## Contributing factors

High rate of nurse rotation within the department.

## Cause analysis

· Lack of established standards for the prescription of medication in the infant unit.
· Absence of checks in the medical orders to verify adequate posology.
· Lack of knowledge with regard to the posology of the medication among some nurses in charge of their administration.
· Absence of computer-based software for medical prescriptions.

## Recommendations

· Reinforce the norms for prescriptions so that the quantity of the active substance is always indicated.
· Elaborate a document with clear information on posology of all the medication employed in the infant unit.
· Establish a procedure that requires verification of the dose before administration with the document on posology.
· Employ an electronically based tool for prescriptions that standardizes the format of medical orders and includes alerts on overdoses.

## Measures

NATIONAL LEVEL (REAL)

Reporting of cases has prompted the Spanish Medicines Agency to emit alerts on related issues and has elaborated a poster for pediatric units in hospitals (http://www.aemps.es/actividad/notaMensual/2010/marzo2010/nota_medicamentos.htm).

HOSPITAL LEVEL

· Reinforce the norm on the necessary information that should appear in the medical orders.
· Introduce a clear norm that all medical orders where the minimum required data does not appear, or is illegible, should be returned by the nurse to be completed before any medication is administered.
· Introduce software for e-prescribing.

**Figure 1.** Diagram of events.

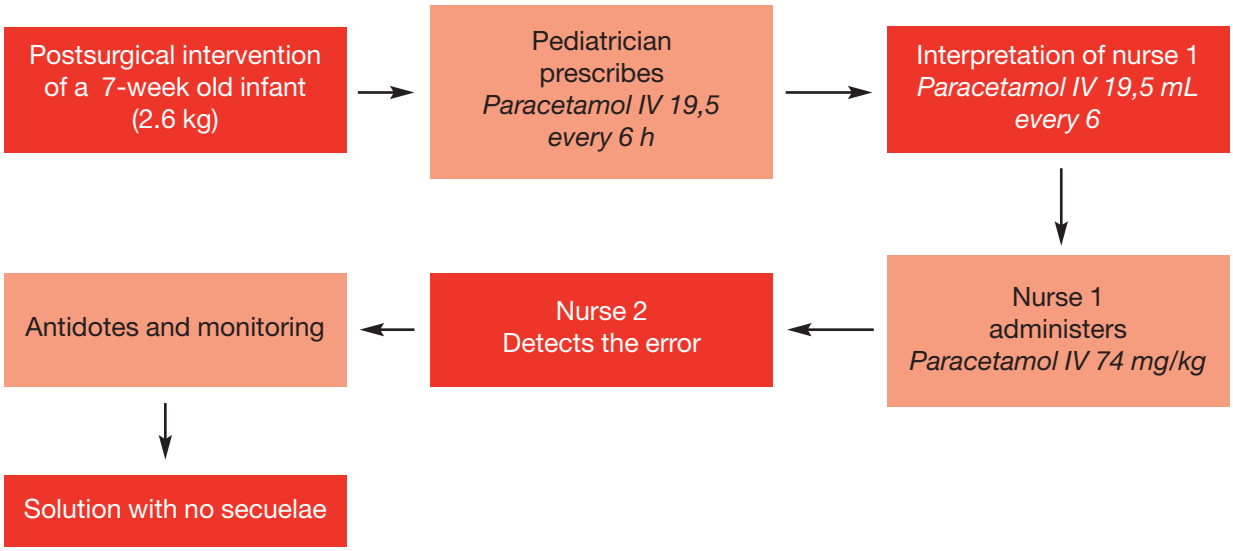

**Table 3.** Stages of root cause analysis.

| | |
|---|---|
| **Identify what incidents need investigation** | Priority is given to those events with severe consequences and those with greater potential for learning. |
| **Form a team** | The responsible in charge should be a respected member of the organization, with experience in this field and certain independence with respect to the event subject to analysis. |
| **Recollect information** | Clinical documentation is recollected and interviews are carried out, while a visit to the site where the event occurred and an examination of the material employed may prove useful.<br>Aspects to recollect:<br>· Brief description of the event.<br>· Who will participate in the analysis.<br>· When the event occurred (date, day of the week, hour).<br>· Which departments were involved.<br>· Create a flow diagram (stages) of the process. It is very useful to identify at what points there may be risk and their contribution to the adverse event.<br>· Important human factors related to the event (fatigue, stress, drug abuse, non-compliance with procedures).<br>· Determine whether the technical equipment affected the result (list all the equipment used in the process and verify functioning and maintenance).<br>· Determine whether there were uncontrollable external factors (eg, breakdown of the information system)<br>· Other areas or departments affected, where the event may also occur, due to similar risk factors.<br>· Level of competence and qualification of all personnel. It is important to respond to the question: were there untrained individuals on duty for specialized tasks?<br>· Levels of personnel (ratios of personnel). Observe whether the event occurred during a holiday period, or weekend. Other aspects to consider include work overload, and changes in schedules.<br>· How personnel are substituted or how contingencies are covered (extra hours, temporary contracts).<br>· Availability of all the information when needed and which should be clear (eg, allergies not recorded).<br>· Levels of communication among participants (adequate or not). Determine whether verbal and written communication was understood.<br>· Adequacy of the physical environment (space, safety and easy access, temperature and humidity, lighting, noise levels, etc.).<br>· Degree of management culture to identify and reduce risk. Does it exist and is it facilitated? Are risk areas identified? Is the prevention of AE a priority? |
| **Mapping the events** | Describe the chain of events that led to the incident. |
| **Analysis of the information** | |
| **Analyze the barriers that can prevent harm** | These may be *physical* like bar codes, computer software that impedes advancing in the process, incompatibility with administration systems. |
| **Development of solutions and a plan for solutions** | Or they could be *administrative*, for example, norms and procedures, alerts, double signature requirements. |
| **Conclude with a report and share learnt lessons** | The report should summarize the above mentioned sections, be simple and easy to read, and not contain information that could result in identification of the personnel involved in the incidents. |

UNIT LEVEL

· Prepare a list of drugs employed in the unit with posologies and corresponding volumes. It should always be visible and available at any moment.
· Establish a procedure that involves posology verification for every drug before administration.

## CASE 2

### Possible errors detected

When prescribing a treatment the possible interaction with cilostazol and proton pump inhibitors was not taken into account.

### Questions that arise

Was the patient's current medication known to the health professional?
Is there any system to detect possible interactions?
Is there any way to manage the increase in risk of adverse reactions caused by the interaction?
Is cilostazol's profile regarding adverse reactions, interactions or precautions to take known by health professionals?

### Analysis of causes

There is no system that automatically alerts the health professional when two drugs prescribed interact.

According to the format in which the clinical records are written there is no way to tell what the current medication of the patient is.

A 50 mg presentation is not marketed in Spain, which is the recommended dose given in the Summary of Product Characteristics in cases where drugs that inhibit the CYP2C19 isoenzyme are employed (for example proton pump inhibitors). *"A dose reduction to 50 mg b.i.d could be considered based on the individual clinical and tolerance response".*

Possibly there exists lack of knowledge of the interaction and therefore there is a need to take extreme precautions.

### Recommendations

Market a 50 mg presentation or modify the Summary of Product Characteristics to allow for correct management of the risk of interactions with other drugs.

Implement programs that detect interactions automatically which could be a useful tool for health professionals.

Facilitate at any moment information regarding the patient's current medication.

Knowledge of the most frequent adverse effects of cilostazol, contraindications, precautions and interactions with other drugs should be available.

### Measures

NATIONAL LEVEL

A petition to the Ministry of Health and Social Policy to demand the marketing of a 50 mg presentation or if not, to modify the Summary of Product Characteristics report proposing another strategy to reduce the risk of an adverse effect.

AT HEALTH SERVICE LEVEL

Proposals:
· Introduce a program to detect and inform about the drug interactions with clinical implications.
· Modify computer software so that at any point of the health care system (specialized, emergency or primary care), information regarding the patients current medication is quickly and easily available to all health professionals.

PROFESSIONAL LEVEL

A note reminding professionals of the characteristics of the drug, adverse effects, interactions, contraindications and precautions should be sent.

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## Conclusions

**Health care is complex and medication is an important cause of harm when not employed adequately.**

**Humans commit errors. We have to learn from our errors to create safer health care.**

**There are tools to prevent medication errors which is a never ending task, although solutions must be found for problems detected.**

**Safety should be a priority for health systems and for all of its members.**

**Patients bear the suffering from medication errors and thus they should be implicated in their prevention.**

## Useful websites

Ministerio de Sanidad y Consumo. Agencia de Calidad. Seguridad del Paciente. http://www.msc.es/seguridaddelpaciente.es

Instituto para el Uso Seguro de los Medicamentos. Delegación española del Institute for Safe Medication Practices (ISMP). http://www.ismp-espana.org

Consejería de Sanidad. Comunidad de Madrid. Uso Seguro de Medicamentos y Productos Sanitarios. https://www.seguridadmedicamento.sanidadmadrid.org/

ISMP Canada. http://www.ismp-canada.org

Canadian Patient Safety Institute. www.patientsafetyinstitute.ca

NHS. National Patient Safety Agency. http://www.npsa.nhs.uk/

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**INFORMATION AND SUSCRIPTION**
Servicio Navarro de Salud / Osasunbidea
Plaza de la Paz, s/n
31002 Pamplona
**T** +34 848429047
**F** +34 848429010

**E-mail**
farmacia.atprimaria@cfnavarra.es

**Web site**
www.dtb.navarra.es