Causes for discontinuing antiretroviral treatment within the first year in PSITAR HIV cohort

Co-authors
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Background
Treatment modifications during the first year after starting antiretroviral treatment (ART) were extremely important. The first ART regimen should remain years. First regimen toxicity can have a negative impact on adherence and virologic efficacy.

Purpose
To establish the main reason for discontinuing antiretroviral treatment within the first year in a HIV cohort.

Materials and Methods
Prospective multicenter study. Naive adult HIV patients who started treatment in 2011 were selected. Basic demographic characteristics (sex and age) and pharmacotherapeutic variables as initial ART, discontinuation of ART within the first year and its reasons based on Swiss HIV Cohort (Elzi et al. Arch Intern Med. 2010) are collected. The main reason for treatment modification was classified as treatment failure, intolerance and/or toxic effects, the patient’s choice, the physician’s decision, and other reasons.

Results
108 patients started ART in 2011, 83% men. The mean age was 40 ± 11. The most frequent ART was emtricitabine/tenofovir/efavirenz (61%) followed by emtricitabine, tenofovir, atazanavir/ritonavir (16%), emtricitabine, tenofovir, darunavir/ritonavir (12%) and others combinations (11%). During the first year of ART, 28 individuals modified their treatment. The reason for treatment discontinuation was: 60% intolerance or toxic effects, 18% treatment failure, 14% the physician’s decision and 8% other reasons. 17 patients modified their treatment because of drug intolerance and/or drug toxicity. Gastrointestinal tract intolerance was the most frequent toxic effect (29.4%), followed by rash (23.5%), hypersensitivity (17.6%), psychiatric events (11.7%), and others (17.8%). Emphasize that 28% of patients discontinued treatment more than once in the first year being especially important in gastrointestinal tract intolerance group.

Conclusions
The number of patients with discontinuation of ART in the first year is acceptable. It is necessary to properly assess starting ART to reduce adverse involving changes in the treatment.

No conflict of interest

Keywords
HIV; discontinuation; ART;

Authors' letter
We attach the abstract entitled "Causes for discontinuing antiretroviral treatment within the first year in PSITAR HIV cohort" for consideration as "Original abstract" in the 19th Congress of the EAHP. PSITAR HIV cohort has a new platform for collecting data on HIV patients, that have great relevance in the current pharmaceutical care as biochemical and virological parameters, adherence, resistance and treatment modifications. Treatment modifications during the first year after starting antiretroviral treatment (ART) were extremely important. In fact, the main Spanish study group of AIDS (GESIDA), in their consensus documents, considers the change of ART treatment within the first year as an indicator of low quality. The first ART regimen should remain years. First regimen toxicity can have a negative impact on adherence and virologic efficacy. A high percentage of first treatment changes may reflect an insufficient counseling activity previous to initiation of ART. This point can be improved to reduce the changes of the first treatment and improve adherence.

Score: 240

Remarks all reviewers:
Santolaya, Rosario: Conclusion warranted

Accepted, but Author modifications

Modifications needed: ;
Nominee: No

The purpose of the study is not in accordance with conclusions. It should be formulated in terms of assessing the percentage of discontinuations of treatment and identification of the main reason in order...
BARI4-0393  
Medications not available in the hospital as a potential risk of adverse drugs events

Co-authors
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Background
The reconciling process of medications not available in the hospital has been demonstrated to be a powerful strategy to prevent from adverse drug events.

Purpose
To evaluate drug prescription and administration errors after medication reconciliation (MR) involving medications not available in the hospital (MNAH) prescribed prior to admission.

Materials and Methods
We conducted a cross-sectional, observational study in an academic medical center using computerized physician-order entry (CPOE). After MR at admission, when clinicians decided that these medications need to be continued during hospitalization, since they are not included in the CPOE database, they are prescribed as a generic product, ‘MNAH’ with the drug name and dosage. The main outcome measured were medication errors involving MNAH detected in prescription and administration phases.

Results
We analyzed 338 MNAH prescribed to 207 inpatients, mainly for chronic cardiovascular diseases. We detected 211 prescription errors (62.4%, 95%CI: 57-67.6) most of them related to administration route and dose and 47 drug administration errors (13.9%, 95%CI: 10.4-18). Omission was the principal type of error in both cases. The main causes of these errors were CPOE program deficiencies (62.1%, 95%CI: 55.1-68.6) and lack of information about medication history in medical records (31.3%, 95%CI: 25.1-38). Most errors did not reach the patient or reached the patient without causing any harm. Errors that caused harm to patients were due to drug duplicity. Clinicians considered that 65.9% (95%CI: 59-72.2) of errors were avoidable by improving CPOE characteristics.

Conclusions
Errors associated with prescription and administration of MNAH after MR are prevalent among adult inpatients. Our results suggest that there are three main weak points: i) lack of coordination and available information for clinicians about medication history of patients, ii) CPOE deficiencies related to MNAH prescription and iii) lack of standardization in the phases of the process of medication use which increase likelihood of failures.

No conflict of interest

Keywords
medication reconciliation;medication errors;drug administration;

Authors letter
Relevance: The administration of drugs prescribed prior to admission that are not available in the hospital formulary plays an important role in the prevention from severe adverse drug events that could cause harm to the patients. Innovation: Many examples available in the literature have proven that reconciliation of medication is an powerful tool to reduce the risks associated to drug administration at admission. There is little evidence and a very few reports about the process of reconciliation on medication not available in hospital formularies. Implication for future hospital pharmacy practice: The results of this innovative study may lead to changes in the current policy of transition of care that may prevent and avoid a large number of adverse drug events.
Background

Previous studies reported an error rate between 11.7% and 49.0%. Off-label use and diluting medications increase the risk of error on pediatric patients, in addition to developmental differences among children. Health care organizations are developing strategies in an attempt to reduce those errors, caused by many factors involving many people.

Purpose

The aim of this study was to determine overall incidence and incidence for stages of medication errors (transcription, storage, preparation and administration stages) in a hemato-oncology pediatric ward.

Materials and Methods

We conducted a descriptive observational study of drug administrations in a hemato-oncology pediatric ward of a large teaching tertiary hospital in Spain. Data were collected on 21 days, including weekends, between February and March of 2013 and they were analyzed by SPSS statistic software. Medication errors were classified according with the updated classification of the Ruiz-Jarabo group (Otero et al., 2008). The error rate was calculated considering the number of doses with one or more errors as numerator and total opportunities of error (TOE) as denominator. TOE is defined as the total number of doses given, whether correct or incorrect, plus omitted doses.

Results

23 patients (52.2% female, 47.8% male, 6.0 [3.0-10.0] years old) were observed. Of 1116 doses administrated, 302 had at least one error; so error rate was 21.7% (95%, CI: 24.1%-30.3%) and 24.1% excluding wrong-time errors. Stages with higher error rate were preparation (43.8%) and storage (32.3%). Most common errors were related to photoprotection (66.7%), timing errors (15.8%) and incorrect preparation of suspensions (10.5%). Pharmacological groups with higher error rate were cardiovascular (100.0%), gastrointestinal (61.9%) and nervous system (49.3%).

Conclusions

The error rate we obtained was similar to those published before. Most common errors were related to failures in working protocols because drug photoprotection is not performed under any circumstances.

No conflict of interest

Keywords
medication errors; pediatry; safety;

Authors letter

In 2005, the Spanish Health Ministry promoted the National Study of Adverse Effects related to hospitalization (ENEAS study). It was a retrospective study of cohorts with a 5624 patients’ sample that was conducted in 24 Spanish hospitals. This study demonstrated that more than 35% of adverse events observed were related to medication. Five years later, in 2010, the Spanish Health Ministry published a National Quality Plan2, that gathered on its strategy number 8 the importance of taking steps and developing protocols to improve patients safety. It considered safety as one of the principal components...
Santolaya, Rosario: Conclusion warranted

Remarks all reviewers:

Score: 200


BILATERAL SUBDURAL HEMATOMA IN AN ANTICOAGULATED PATIENT TREATED WITH DABIGATRAN

Co-authors
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Background
Dabigatran is a new drug to prevent the formation of blood clots in the veins in adults who have had an operation to replace a hip or knee and prevent stroke and the formation of clots in adults who have an abnormal heart beat (non-valvular atrial fibrillation).

Purpose
To describe a case report of a bilateral subdural hematoma secondary to traumatic brain injure (TBI) in an anticoagulated patient treated with dabigatran and a fatal outcome.

Materials and Methods
Patient’s medical history review. Product information: dabigatran

Results
84-years-old female, with hypertension, paroxysmal atrial flutter, cardiopathy, light pulmonary hypertension, toxic goitre, trigeminal neuralgia, gastroesophageal reflux. Surgical record: cholecystectomy, cystoid. Usual treatment: enalapril, amlodipine, furosemide, dabigatran 110mg/12h (November’11), digoxin, oxygen, radiactic iodine, pregabalin, metamizole and omeprazole.

In April’12, the patient came to Emergency Department (ED) due to a sudden memory loss with TBI, Glasgow 15 but she was dizzy. Patient presented high blood pressure (180/80 mmHg) and 78 beats/minute. Blood analysis: neutrophilia, prothrombin time 19.1 seconds, APTT 64.3 seconds, INR 1.6. Patient showed heart failure in radiography of thorax and bilateral subdural hematoma in computed tomography axial (CTA). As consequence, ED commented this case with Neurosurgery Department of a reference hospital.

She was treated with prothrombin complex concentrate(600 UI) and enoxaparine(60 mg) and she was traslated to Neurology Department, where the patient got worse, in a few hours, with Glasgow 3-4. A new CTA was requested but the patient died before.

Suspected adverse drug reaction was reported to the Regional Center of Pharmacovigilance.

Conclusions
Patients with oral anticoagulants treatment should be controlled because of the haemorrhage risk. This monitoring should be exhaustive whether new drugs are involved, such as dabigatran. Essays after marketing authorization and antidote researches are the key to ensure oral anticoagulants security. Health professionals should communicate adverse events to improve drug security and efficiency.

No conflict of interest

Keywords
Dabigatran; Hematoma; antidote;

Authors letter
Dabigatran is a new oral anticoagulant treatment. Health professionals should control this drug because of its haemorrhage risk. This abstract tells us how one patient died because of she was treated with dabigatran and she suffered from haemorrhage which did not stop due to dabigatran does not have antidote.

Score: 240

Remarks all reviewers:
Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Rejected
10.
Reason for reject: ;
No causality assessment
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1. Modifications needed: ;
Nominee: No

5/21
BARI4-0423

The use of potentially inappropriate medications among elderly patients with low-energy hip fractures

Co-authors
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2University of Szeged, Traumatology Department, Szeged, Hungary.

Background
Many studies have proven that polypharmacy - chronic use of at least 5 medications - is one of the major risk factors of low-energy-falls. The most significant consequence of low-energy-falls is hip fracture, responsible for high morbidity and mortality rates. Several Potentially Inappropriate Medications (PIM) lists were used to evaluate the drug use (and possible exposure to falls) among elderly patients with hip fractures, such as Beers or Priscus list.

Purpose
To identify some of the main risk factors (polypharmacy, anemia) of low-energy-falls and to examine their impact on the outcomes (length of hospital stay, mortality) of hospitalization.

Materials and Methods
A retrospective analysis was done, regarding patients admitted to the Traumatology Department (Szeged, Hungary) with low-energy hip fractures between January 2011 and March 2012. Patients were identified according to ICD codes (International Classification of Diseases, S7200, S7210, S7220) and age (over 50 years).

Results
Out of 386 patients (100 males, 286 females; mean age 79.4 years, SD±9.5 years), polypharmacy occurred in 71%. The mean number of chronic medications was 6.8 (SD±3.8). We found that 55.3% of female- and 66.3% of male patients were anemic at admission. According to the PIM lists, two-third of the patients were taking at least 1 medication with potential side effect of fall, 34% at least 2 or more at the moment of fracture. Those who were taking 10 or more medications (95 patients, 24.6%), had longer hospital stay than non-takers (14.5 days versus 11.9 days). The mortality was 2.8% in women, 7.0% in men during the hospital stay. The average number of chronic medication was 8.3 (SD±2.7) among deceased patients, 1.5 medication above average.

Conclusions
Linear tendency between the number of medications taken, hospital stay and mortality was seen, but wasn’t statistically significant. These factors have impact on clinical outcomes. Larger patient number would be necessary to verify the correlation between our findings.

No conflict of interest

Keywords
Hip fracture; Polypharmacy; Potentially Inappropriate Medication;

Authors letter
There are approximately 18,000 osteoporotic hip fractures in Hungary each year, which put a huge burden to the patient and also to healthcare providers. To reduce the incidence of low-energy falls- and consequently fractures - our aim is to explore the most significant risk factors of falls and make healthcare professionals aware of them as well as for the population at risk (i.e. elderly people).

Score: 220

Remarks all reviewers:
Santolaya, Rosario:
Rejected
8.
Reason for reject: ;
The purpose of the study is to identify risk factors and impact on outcomes but these cannot be done without a control group or an regression analysis

Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: Yes

BARI4-0425

DRUG ADVERSE EVENTS (DAE) IN SPANISH HOSPITALS

Co-authors
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Background
Specific studies focusing exclusively on DAE show different values in incidence and nature of the reported events. Evidence from general adverse events studies has never been analysed in Spain.

Purpose
To evaluate the DAE identified in two Spanish Regional studies and the Spanish National Study of Adverse Events (ENEAS) determining its impact and preventability.

Materials and Methods
Case series analysis. A database of 9320 records of patients taking part in three retrospective cohort studies aimed to identify Adverse Events (AE) associated directly with medical care in Spain, was searched to identify DAE. Descriptive statistics were used.

Results
A series of 271 DAE was identified. 112 (41.5%) were considered medication errors, therefore preventable and 158 (58.5%) classified as Adverse Drug Reactions (ADR). Errors involving drug-related clinical monitoring reached 50.0%, prescription errors 46.7%, and administration errors (more difficult to identify in medical records) 3.3%. Improper fluid replacement was responsible of 10.7% of the errors.

Half of the DAE were related to Intravenous administration. 22.9% of events involved antibiotics. The ADR analysis showed 43.8% of gastrointestinal AE, 14% of Haematological AE and 12% of Cardiovascular AE.


Conclusions
The most frequent problems are digestive ADR and overdosage. A large proportion are preventable errors. The difference in incidence observed with specific studies focusing exclusively on DAE shows that little information allowing DAE identification is contained in medical records, but this register is of great value allowing the emergence of underreported errors in specific studies like those related to fluid replacement.

No conflict of interest

Keywords
medication error; adverse drug reaction; safety.

Authors letter
1) RELEVANCE Data from general studies focused on adverse events related to hospital admission could rise new evidence to complete the one found in specific drug adverse events (DAE) studies
2) INNOVATION Never before DAE data from a national study have been analysed in Spain
3) IMPLICATIONS FOR FUTURE HOSPITAL PHARMACY PRACTICE The new evidence provides professionals with more data to look for underreported DAE and underlines the convenience of filling complete medical records

Score: 220

Remarks all reviewers:
Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No
typographic errors (?)
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.5.
Modifications needed:
Nominee: No
Explain better the source of information for DAEs.

BAR14-0478
Pharmaceutical intervention in recommendations for the use of enoxaparin in patients with impaired renal function

Co-authors
11/4/13
7/21
Background

Enoxaparin is an anticoagulant used for the treatment and prophylaxis of thromboembolic disease. It's excreted via the renal route. In situations of renal failure, increases its half-life, so their elimination clearance is reduced and may increase the risk of accumulation and bleeding.

Purpose

Ensure, through pharmaceutical intervention (PI), a proper dosage of enoxaparin in patients with chronic kidney disease, suggesting dose adjustment according to renal function.

Materials and Methods

Prospective study for three months in a tertiary hospital. Patients treated with low 40 mg enoxaparine where revised. Creatinine clearance (CrCl) < 30ml/min induced PI. PI consists in: 30 mg Enoxaparin on prophylaxis and 1mg/kg/day on treatment of venous thromboembolism, unstable angina and acute non-Q wave myocardial infarction. All interventions were reported to physician by a report in electronic prescribing program (Unidosis Farmatools® software application Dominion®). PI were not performed when the patient's anticoagulation were followed up by the hematology department. Data were obtained from electronic prescribing (Unidosis Farmatools® software application Dominion®), laboratory program (GIPI®) and electronic medical records (ARIADNA®).

Results

During the study, enoxaparin has been prescribed in doses above 40 mg / day to 192 patients. 12 (6.25 %) had a CrCl < 30ml/min. PI were performed in 83.3 % (10) of the cases, being accepted by 80 % (8). Reasons for not accepted PI were patient discharge and renal function recovery.

Conclusions

PI allowed for appropriateness of prescribing, promoting a safe and proper use of enoxaparin, improving patient safety and reducing the risk of complications associated with overdosage, with the consequent impact on the efficiency and quality of care of hospitalized patients.

Conflict of interest:
Enter Yes or No: No

Keywords

enoxaparin;renal impairment;adjustment;

Authors letter

This study is relevance because promotes patient safety and the proper use of medication. It is innovative in our hospital since there had been a similar study before. The aims of this work is establish a protocol for enoxaparin appropriate prescribing in patients at risk such as patients with renal failure.

Score: 240

Remarks all reviewers:

Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Accepted Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.4.
Modifications needed: ;
Nominee: No

Purpose should be like "to describe the impact of pharmaceutical intervention on prescribing habits in patients treated with enoxaparin and impaired renal function"
Materials and Methods

Descriptive prospective observational study in September 2013 in patients admitted to Cardiology Unit in a tertiary hospital. Demographic data studied: sex and age. Patient’s usual chronic treatment, obtained by comprehensive interview to the patient and by clinical history revision, was compared with admission medication orders in order to identify: No Discrepancies (ND), Intentional Discrepancies (ID) (formulary substitutions/modifications in response to patient’s clinical status) and apparently unexplained Discrepancies Requiring Clarification with the physician (DRC). After clarification, Reconciliation Errors (RE) (discrepancies resulting in physician order changes) were classified by type and severity.

Results

75 patients admitted. Only 25 were reconciled due to logistic reasons. The median age was 74.9±8.9 years. 64% were male.

315 analyzed medications: 75 ND (23.81%), 193 ID (61.27%) and 47 DRC (14.92%).

After clarification, 37 (78.72%) DRC were RE. 11.75% of prescriptions (37/315) were RE.

RE affected 19 (76%) of the study patients. The average of RE per patient was 1.95.

Types of RE were: omissions (n=25), different dose/route/frequency (n=3), unnecessary medication (n=2), wrong medicine (n=1) and incomplete prescription (n=6).

In terms of severity, RE were distributed as follows: No error, but possible (n=8), error that does not reach the patient (n=22), error reaching but not harmful (n=6) and errors that caused temporary harm requiring intervention (n=1).

Conclusions

The process of developing a pharmacotherapeutic history at hospital admission is inadequate since three out of four patients showed RE, mostly omissions.

Although most of RE caused no damage, if perpetuated at discharge, they might have worse consequences and/or affect the effectiveness of treatment. The pharmacist’s work in hospitalization units is vital to reduce errors in care transitions and represents an opportunity to develop pharmaceutical integral attention in order to increase patient safety.

No conflict of interest

Keywords

Reconciliation;error;safety;

Authors letter

Grade of relevance: The medication reconciliation process detects medication errors and has demonstrated to be a key point to increase patient safety. Although most of RE caused no damage, if perpetuated at discharge, they might have worse consequences and/or affect the effectiveness of treatment. Grade of innovation: The medication reconciliation process is an innovative, but still not a compulsory strategy in our Health System. Our abstract shows that the process of developing a pharmacotherapeutic history at hospital admission is inadequate since three fourths of patients showed medication errors. Therefore, this strategy must be continued and should not remain as a simple isolated study. Grade of implication for future hospital pharmacy practice: The pharmacist’s work in hospitalization units is vital to reduce errors in care transitions and represents an opportunity to develop pharmaceutical integral attention in order to increase patient safety.

Grade of innovation: The medication reconciliation process is innovative, but still not a compulsory strategy in our Health System. Our abstract shows that the process of developing a pharmacotherapeutic history at hospital admission is inadequate since three fourths of patients showed medication errors. Therefore, this strategy must be continued and should not remain as a simple isolated study.

Grade of implication for future hospital pharmacy practice: The pharmacist’s work in hospitalization units is vital to reduce errors in care transitions and represents an opportunity to develop pharmaceutical integral attention in order to increase patient safety.

Score: 200

Remarks all reviewers:

Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Accepted Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Rejected
2.5.
Reason for reject: ; ;

BART14-0492

TETRAHYDROCANNABINOL-CANNABIDIOL: USE IN A GENERAL HOSPITAL

Co-authors

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Background

Tetrahydrocannabinol-cannabidiol (THC) is the first drug derived from the cannabis plant. THC is licensed as an add-on treatment for patients with multiple sclerosis (MS) and spasticity.

Purpose

To evaluate THC effectiveness and safety to treat patients with spasticity.
Materials and Methods
Retrospective study (June 11-July 13) of patients which have been treated with THC. Data collection: patient’s medical and pharmacotherapeutic history review, age, genre, diagnosis, start date, treatment duration, number of pulverizations/day, previous and concomitant treatment, adverse effects (AE) and treatment effectiveness (decrease spasticity/stiffness).

Results
During the study, 18 patients received THC, 10 women, mean age 53 ±13 years. Twelve patients diagnosed MS, 16% for global patients MS, (5 secondary-progressive, 2 primary-progressive, 5 relapsing-remitting), 3 spastic paraparesis, 1 static anoxic encephalopathy, 1 generalized spasticity and 1 left hemidystonia. These six patients were processed following Spanish legal rules (RD 1015/2009). Study closing, ten patients continued their treatment (8 MS) (medium number of pulverizations/day 6±2, medium time with treatment 16±10 months). The rest of patients left treatment because of inefficacy (2), intolerance (2), incompatible comorbidity with treatment (1) and other unknown causes (3). Before THC treatment, 11 used other drugs: botulinum toxin(3), tizanidine and/or baclofen (8). 13 patients use concomitant treatments with tizanidine(5), baclofen(4) and both(4). Treatment was effective in 10 patients: 8 patients decreased their spasticity and 2 their stiffness. 4 patients presented AE: 2 treatments were suspended, 1 decreased dose and 1 divided daily dosage in two times.

Conclusions
THC has demonstrated effectiveness to treat spasticity related to MS or not in more than half of cases. As far as the security THC is concerned, only 4 patients presented AE and 2 of them left their treatment. But, health professionals should monitor patients.

More studies are necessary to identify groups of patients who can benefit from treatment with THC and patients which could develop AE.

Conflict of interest:
Enter Yes or No: NO

Keywords
Tetrahidroccannabinol-cannabidiol, Multiple sclerosis, Spasticity,

Authors letter
Tetrahydrocannabinol-cannabidiol is a new drug to treat patients with multiple sclerosis and spasticity. This drug was authorized in 2010. It is very important, from Outpatient Pharmacy Department, to make a strict control with such a little experience of use drug.

Score: 180

Remarks all reviewers:
Santolaya, Rosario:
Accepted, but Author modifications
2.
Modifications needed: ; Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Rejected
4.
Reason for reject: ;

BAR14-0493
role of pharmaceutical intervention in elderly patients with hip fracture

Co-authors
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2hospital de la vall d’hebron, internal medicine, barcelona, Spain.

Background
Hip fracture is a major public health problem with a high incidence and prevalence in people over 65 years old. This group of patients presents changes in body composition and organ function, an important situation of co-morbidity, and they are usually polymedicated, which imply a greater chance of drug related problems. All of that should be taken into account in the pharmaceutical care.

Purpose
The aim of this study is to analyze pharmacological treatment of elderly patients ongoing hip fracture in order to improve pharmaceutical care in this group of patients.

Materials and Methods
A prospective pilot study was performed during two months (August-October, 2013) with patients
admitted in a tertiary hospital ongoing hip fracture. These variables were recorded for each patient: sex, age, length of hospital stay, neuropsychiatric problems, residential status, actual diseases and renal function. Drug treatment was recorded from pharmacy database (Silicon®).

Drugs were classified in seven different groups: Not adjustment required (N), Adjustment required for renal function condition (AR), Adjustment required for elderly condition not related with renal function (AG), Adjustment required for both elderly and renal function condition (AB), Precaution in elderly patients (P), Not enough information in geriatric population (NI), and Inappropriate based in Beer’s criteria (I).

On a second phase, a pharmacist experienced on geriatric population revised all of the prescriptions on every patient and determined if drugs that needed dosage adjustment were adjusted or not.

Results

Forty hip fracture patients were included in the study, 75% women and 25% men, with a mean age of 85 years (73-102). 47.5% of the patients lived at home and 20% were institutionalized. The average number of actual diseases was 6 (1-13); 15% of the patients had neuropsychiatric problems. On average they stayed 16 days in the hospital (7-28), and received 14 drugs (6-20). About renal function, 7.5% of the patients presented a creatinine clearance below 30ml/min, and 35% presented it between 30-60ml/min.

We analyzed 553 prescriptions, which included 117 drugs and were classified in seven different groups: N: 46 drugs (39%), AR: 26 drugs (22%), AG: 9 drugs (8%), AB: 4 drugs (3%), P: 19 drugs (16%), NI: 9 drugs (8%) and t: 4 drugs (3%).

On average, each patient had a dosage adjust of the 84% on those drugs that needed it.

In 3 patients the dosage adjustment was made on less than the 40% of the drugs that needed it and 29 patients had an 80-100% correct adjustment.

Conclusions

Dosage adjustment or precaution was required in the 53% of the drugs prescribed and 42% of them needed adjustment according to renal function.

A correct dosage adjustment was done on the 84% of those drugs in average on each patient. Only few patients had an adjustment done below the 40%, and almost a third of the total number of patients had adjustment 80-100% done.

It’s necessary to include the role of the pharmacist in the multidisciplinary team in elderly patients ongoing hip fracture in order to ensure a correct adjustment of the pharmacological treatment and avoid potentials drug related problems.

No conflict of interest

Keywords

hip fracture; Geriatric pharmacology; Pharmaceutical care;

Authors letter

• The physiological changes of aging, the high intake of medicines, the presence of multiple diseases, the issues regarding treatment adherence, the changes in the nutritional status and psychosocial problems increase the risk of drugs side effects and reflect the importance of taking an special pharmaceutical care on elderly patients. • With the increase of live expectancy, there’s an important part of the population above the 85 years old and polymedicated, and the experience in such old ages it’s not tested or studied in many drugs, so there’s still a lack of information about that group of patients. • It's important to include the role of the pharmacist into the multidisciplinary team in order to optimize the treatment on elderly patients with hip fracture.

Score: 240

Remarks all reviewers:

Santolaya, Rosario:

Accepted, but Author modifications

4.

Modifications needed: ;

The purpose of the study is too wide and should be specified that only doses are analysed. Also title should be in accordance with variables analysed

Venturini, Francesca: Conclusion warranted

Accepted

Nominee: No
Background
Biosimilar medicines are independently developed after the patent protecting the original product has expired. These substances are followon versions of original biological medicines, which are produced using a living system organism as DNA recombinant technology.

Purpose
To compare the results of efficacy and safety in prophylaxis of neutropenia by chemotherapy during six months between a biosimilar of filgrastim and filgrastim original active substance.

Materials and Methods
Observational study, including all patients treated with cytotoxic chemotherapy for malignancy who have received human granulocyte-colony stimulating factor (G-CSF). From July 2011 to December 2011 we had filgrastim original active substance and from July 2012 to December 2012 we had a biosimilar of filgrastim.

The following variables were included: number of patients (n), nº of dispensations per patient, nº of syringes per chemotherapy by cycle, nº of febrile neutropenia episodes and adverse reactions.

Results

<table>
<thead>
<tr>
<th></th>
<th>From July 2011 to December 2011</th>
<th>From July 2012 to December 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>The number of patients (n)</td>
<td>217</td>
<td>312</td>
</tr>
<tr>
<td>The average of dispensation per patient</td>
<td>3,77</td>
<td>3,79</td>
</tr>
<tr>
<td>The average of syringes per chemotherapy cycle</td>
<td>4,87</td>
<td>4,53</td>
</tr>
<tr>
<td>The average of febrile neutropenia episodes in patients</td>
<td>15 (6,91%) 8 of them required admission to the hospital</td>
<td>9 (2,88%) 7 of them required admission to the hospital</td>
</tr>
</tbody>
</table>

No conflict of interest.

Keywords
Biosimilar; Filgrastim; Technology;

Authors letter
Ms. Elena V. Tortajada Esteban Hospital Universitario Fundación Jiménez Díaz Pharmacy Avenida Reyes Católicos, 2 28040 Madrid Spain

Score: 180

Remarks all reviewers:
Santolaya, Rosario:
Rejected
1.
Reason for reject: ;
No data about the cytotoxic chemotherapy of both groups so we do not know if patients are comparable
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.
Modifications needed: ;
Nominee: No

authors are missing
Use of venous thromboprophylaxis in critical illness in a traumatic intensive care unit (ICU)

Co-authors
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1Hospital Vall d’Hebron, Pharmacy, Barcelona, Spain.
2Hospital Vall d’Hebron, Intensive (Neurotraumatic ICU), Barcelona, Spain.

Background
Venous thromboembolism (VTE) is a common and potentially lethal complication of hospitalization. Critically ill patients have multiple risk factors for VTE such as prolonged immobility, use of central venous catheters, mechanical ventilation or related to comorbidities. To reduce the incidence of VTE, various pharmacologic and mechanical thromboprophylaxis (TP) methods are available.

Purpose
The purpose of this study was to characterize the prophylactic strategies used in a cohort of critically ill patients during their ICU length of stay (LOS) and their adherence to the hospital guideline recommendations.

Materials and Methods
We conducted a prospective review of all patients admitted to a traumatic and neurocritical ICU from July 2013 to September of 2013. Patients were excluded if they were being treated for VTE, or were therapeutically anticoagulated for other reasons prior to ICU admission. For ICU patients our guidelines recommend anticoagulant TP with low-molecular-weight heparin (LMWH) as soon as it is safe, if it is not contraindicated. However, it is more usual in ICU to start TP using mechanical methods because the high risk of bleeding the early days, in which LMWH are contraindicated.

A high risk of bleeding was defined as symptomatic bleeding, presence of organic lesions likely to bleed, hemophilic diseases, hemostatic abnormalities (platelet count <50000/mm3; aPTT ratio >2; prothrombin time (PT) <40% or severe anemia (hemoglobin <7g/dL) due to bleeding or unexplained.

We collected biodemographic data and other clinical related to VTE.

Results
Over the study period 34 patients were admitted to the ICU, from these 4 were excluded. We therefore enrolled 30 patients, with a mean age of 45.53 years; of which 86.6% were men. The median ICU LOS was 17 days (3-51).

Main reasons of admission were acute spinal cord injury (SCI) (30%), stroke (26.6%) and head injury (23.3%).

From the patients who used mechanical TP (43.75%), 96.6% used intermittent pneumatic compression (IPC) and 3.3% used graduated compression stockings (GCS). The mean to start treatment (MST) was 1.7 days, and the mean of treatment period (MTP) was 12.3 days.

Of the patients treated with LMWH (84.3%) (all adjusted according to renal function):
- 50% received both, first mechanical and then pharmacologic treatment, with a MST of 13.7 days and a MTP of 11.9 days.
- 50% received as a first line treatment LMWH, with a MST of 5.4 days and a MTP of 8.7 days.

The main reason for unsafe LMWH treatment and prolong mechanical measures was head injury (30.8%) and stroke (38.5%).

Of all patients, 4 (13.3%) didn’t receive any TP treatment during ICU LOS.

During the study period any occurrence of VTE was recorded, but we do not know if any event has occurred after patients discharged.

Conclusions
TP methods are necessary to reduce morbimortality associated to VTE, especially in ICU patients because of the multiple risk factors, and each patient must be assessed individually depending on the bleeding risk vs thrombotic risk.

Our ICU has an appropriate adherence to our guidelines. A high percentage of the patients initially received mechanical TP in the first or second day, and started late treatment with LMWH because of the high risk of bleeding, as recommended by our guidelines.

However we believe that there is a small number of patients who should have started the TP earlier, and we should evaluate what has been the cause in order to influence and propose strategies for improvement.

Including a pharmacist in the multidisciplinary team of critical care practitioners in the ICU is necessary to optimize treatments.

Conflict of interest:
Enter Yes or No: NO

Keywords
Venous thromboembolism; thromboprophylaxis; intensive care units;

Authors letter
1. Relevance: Venous thromboembolism (VTE) is a common and potentially lethal complication of hospitalization, especially in ICU patients, and it is necessary to use an optimal thromboprophylaxis.
2. Innovation: Little information is yet available on VTE prophylaxes in the ICU, more studies and information are necessary to the management of this common complication in clinical practice.
3. Implication: It is important to note in ICU patients the multiple risk factors for developing a venous thromboembolism, and the need to use an optimal prophylaxis. Including a pharmacist in the multidisciplinary team of critical care practitioners in the ICU is necessary to optimize treatments.
BARI4-0513
The use of a different amino acidic solution in total parenteral nutrition mixtures for critical newborn: an experience

Co-authors
E. Grande1, L. Infante1, G. Pomero1, E. Dogliani1, A. Isardo1, M. Mandini1, G. Perlo1, P. Gancia2, M. Abate1, M.M. Ferrero1.
1. S. Croce e Carle, Pharmacy, Cuneo, Italy.
2. S. Croce e Carle, Neonatal Intensive Care Unit, Cuneo, Italy.

Background
On request of the intensive neonatal care unit, in order to reduce water supply, we replace the usual aminoacidic mixture TPH® 6% with Primene® 10%. After this change however, a greater frequency of acidosis has been reported from data sourcing from arterial blood gases analysis (ABG).

Purpose
Understand if this change in the mixtures could be the reason of the onset of acidosis.

Materials and Methods
We have analyzed all ABGs data, the compositions of the two products and determined pH and the buffering capacity: 2ml of glucose 50% (acid component of total parenteral nutrition) were progressively added to 50ml of the two products.

Results
The formulations containing Primene® prepared from August to November 2012 have been 179 for 23 babies. We can identify three groups: 12 babies with birth weight >1500 g (A), 6 babies with birth weight 1000 – 1500 g (B1) and 5 babies with birth weight < 1000 g (B2). The ABG data collected were:
(A) pH7.36, Base Excess (BE)-1.20, bicarbonate (HCO₃) 23.5 
(B1) pH7.36, BE-2.46, HCO₃ 22.24 
(B2) pH7.29, BE-7.33, HCO₃ 18
The differences between B1/B2 groups are statistically significant (P<0.0001). We point out that: in TPH® are present acetate ions that in vivo are bicarbonate precursors, responsible for alkaline reserve. Primene® doesn't contain acetate, but a greater amount of chloride ions and acid aminoacids (glutamic and aspartic) and a smaller amount of basic aminoacids (histidine and arginine). The measurement of the buffering capacity of the products showed the same trend of pH, pointing out a similar buffering capacity in vitro, despite a lower pH of departure of Primene® (5.23 against 5.66).

Conclusions
We assume that the absence of the acetate and the presence of chlorides can lead the formulations containing Primene® to have in vivo a different buffering capacity favouring the observed acidosis. The statistical analysis of clinical data highlights a significant difference between newborns (B1) and (B2), which thus have a reduced tolerance to chloride ions' load. From our experience it is not advisable to use Primene® in pre-term weighing <1000 g and it looses interest its use in the other groups, in which the water balance is less critical.

Conflict of interest:
Enter Yes or No: NO

Keywords
acidosis;aminoacidic solutions;newborn;

Authors letter
Our work is relevant because it describes: - an example of tight collaborations between hospital pharmacy and the neonatal intensive care unit - how a little change in the everyday practice can lead to a serious and life threatening clinical problem. About the implication for future hospital pharmacy practice, this experience has taught us to deeply analyze the efficacy and safety of every treatment.
BAR14-0522
The development and optimisation of a clinical rule
Co-authors
B. Van Oijen1, C. Mestres Gonzalvo1, H.A.J.M. de Wit1, K.P.G.M. Hurkens2, R. Janknegt1, P.H.M. van der Kuy1.
1Orbis Medical Centre, Clinical Pharmacy and Toxicology, Sittard-Geleen, The Netherlands.
2Maastricht University Medical Centre, Internal Medicine, Maastricht, The Netherlands.

Background
A Clinical Rule (CR) can be defined as an algorithm that combines different patient related factors (medication, medical history and laboratory values) and generates an alert when specific conditions are present (i.e. hypopotassemia without potassium supplements).

Purpose
To optimise the sensitivity and specificity of the CR ‘Potassium’.

Materials and Methods
The CR ‘Potassium’ has been revised four times since the implementation of the CR database:
1. Generates alerts when potassium affecting medication is used and the potassium level is abnormal (<3.0 mmol/L or >5.0 mmol/L).  
2. The CR is divided in two separate rules:
   - A hypopotassemia rule generating alerts if potassium decreasing medication is used and the potassium level is decreased (<3.0 mmol/L).
   - A hyperpotassemia rule generating alerts if potassium increasing medication is used and the potassium level is increased (>5.5 mmol/L).
3. The clinical rules are further developed:
   - The hypopotassemia rule generates alerts if potassium decreasing medication is used, the potassium level is <3.0 mmol/L, and no potassium supplements are used.
   - The hyperpotassemia rule generates alerts if potassium increasing medication is used, the potassium level is >5.5 mmol/L, and no potassium binder is used.
4. The hypopotassemia CR is adjusted so that alerts are generated if the potassium levels are <2.0 mmol/L, despite the use of potassium supplements.

Results
The number of alerts generated by the CR ‘Potassium’ is decreased with every adjusted CR. At the start of the implementation there were approximately 25 alerts concerning the potassium per day, of which 2–3 required an intervention (adding or stopping potassium affecting medication).

With the latest version of the CR ‘Potassium’ 2–3 alerts are generated per day and all require an intervention.

Conclusions
Daily practice and regular evaluation make it possible to optimise the CR by increasing the sensitivity and specificity.

Conflict of interest:
Enter Yes or No: No

Keywords
clinical rule; clinical decision support system; optimisation;
BAR14-0534

Evaluation of clinical rules in a clinical decision support system for hospitalised and nursing home patients

Co-authors
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2Maastricht University Medical Centre, Internal Medicine, Maastricht, The Netherlands.
3Orbis Medical Centre, Clinical Pharmacy and Toxicology, Sittard-Geleen, The Netherlands.
4ZANOB / Utrecht Institute for Pharmaceutical Sciences Faculty of Science Utrecht University, Hospital Pharmacy / Division of Pharmacoepidemiology and Clinical Pharmacology, ’s-Hertogenbosch / Utrecht, The Netherlands.
5School for Public Health and Primary Care Maastricht University, General Practice and Department of Health Services Research, Maastricht, The Netherlands.

Background
Computerised clinical decision support systems can be defined as an aiding tool which provides clinicians or patients with clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times, to enhance patient care.

Purpose
To improve the currently used clinical decision support system (CDSS) by identifying and quantifying the benefits and limitations of the system.

Materials and Methods
Alerts and handling of the executed clinical rules were extracted from the CDSS in the period September 2011 until December 2011. The data was analysed on the number of executed clinical rule alerts, percentage of relevant alerts and the reason why alerts were classified as non-relevant.

Results
The 4065 alerts have been differentiated into; 1137 (28.0%) new alerts, 2797 (68.8%) repeating alerts and 131 (3.2%) double alerts. For all these alerts, only 3.6% were considered relevant, i.e. when the pharmacist needed to contact the physician. The reasons why alerts were considered as non-relevant were; the dosage was correct or already adjusted, the drug was (temporarily) stopped, the monitored laboratory value or drug dosage had already improved to within the reference range. The low efficiency of the current system can be related to three subjects; the algorithm construction, the CDSS executing the clinical rules and the data delivery to the CDSS.

Conclusions
The results of this study clearly show many points of improvement for the CDSS. We have defined three categories of importance for the efficiency when improving or developing a CDSS: algorithm differentiation, CDSS optimisation and data delivery.

Conflict of interest:
Enter Yes or No: No

Keywords
Clinical Rules; Clinical Decision Support System; Medication review;

Authors letter
The use of a CDSS and clinical rules can improve the quality of medication reviews.

Score: 280

Remarks all reviewers:
Santolaya, Rosario:
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

Score: 200

Remarks all reviewers:
Santolaya, Rosario: Conclusion NOT warranted
Conflict of interest clear
Rejected

1.3.
Reason for reject: ;
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No
Background
Polypharmacy increases the risk of adverse drug reactions and possibly undertreatment.

Purpose
To evaluate to what extent laboratory data, actual medication, medical history and drug indication are interpreted in daily practice.

Materials and Methods
46 health care professionals, including community pharmacists, nursing home physicians, and general practitioners in the Netherlands, were asked to participate in this review. The health care professionals were requested to perform medication reviews for three different cases (A, B and C). Per case, the amount of information provided varied in three subsequent stages: in stage 1 only the medication list was shown; in stage 2 the laboratory data and the reason for admission were added, and in stage 3 the medical history was also included. Following a Delphi method, a multidisciplinary expert panel established the gold standard for each case and stage, by performing the medication review for each case and stage. For each case and each health care professional the number of remarks and their clinical relevance were retrospectively assessed in comparison to the corresponding case from the expert panel, i.e. with the same available information, in order to assess how the information was interpreted.

Results
The average score for the three cases and the three stages was 36.85%. On one hand, medication problems which were identified by few participants included the addition of new medication and switching medication according to clinical data and/or guidelines. On the other hand, dose reduction and/or drug stopping due to laboratory values or lack of indication were well identified.

Conclusions
The large variation in the quality of medication reviews, as well as the low mean quality found in the present study, highlights that information might be incorrectly used or wrongly interpreted, irrespective of the available information.

Conflict of interest:
Enter Yes or No: No

Keywords
Polypharmacy; Medication review; Clinical Decision Support System;

Authors letter
The use of a CDSS and clinical rules can improve the quality of medication reviews.
Background
The development of clinical decision support systems (CDSS) has become an ongoing process of sophistication generating systems that link patient characteristics with computerized knowledge bases by using algorithms (clinical rules) and generating patient-specific assessments or treatment recommendations.

Purpose
To develop a more efficient CDSS by tackling algorithmic differentiation, CDSS possibilities, and data delivery.

Materials and Methods
In early 2011 a multidisciplinary team started developing a CDSS, the CRR (Clinical Rule Reporter). The CRR possibilities were expanded making it possible to integrate the electronic medical record system (medical history and laboratory data) and the computerised physician order entry system (drug record and contraindications). The data delivery was also optimised by standardising the format so that the CRR can interpret more data such as starting/stopping dates, the number of gifts, and the dosage per gift. As for the algorithmic differentiation, evidence and literature based clinical rules were developed making them as sensitive and specific as possible.

Results
In a previous CDSS around 90 alerts were generated per day, of which 3.6% were relevant. In the first CRR version around 55 alerts were generated per day, of which approximately 10% were relevant. After revising and further optimising the CRR, around 35 alerts are generated per day, of which 25% are relevant.

Conclusions
Optimising the CRR implicates a decrease in the number of alerts and an increase of relevant alerts. Constant development and updates are of great importance to further optimise the CRR making it more efficient.

Conflict of interest:
Enter Yes or No: No

Keywords
Clinical Rules; Clinical Decision Support System; Medication review;

Authors letter
The use of a CDSS and clinical rules can improve the quality of medication reviews.

Score: 180
Remarks all reviewers:
Santolaya, Rosario: Conclusion NOT warranted
Conflict of interest clear
Rejected
9.
Reason for reject: ; Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

BARI14-0561
Toxicity assessment of first-line treatment in metastatic colorectal cancer

Co-authors
A. Escolano1, C. Pérez1, O. Pascual1, I. Larrodé1, V. Gimeno1, M.J. Agustín1.
1Universitary Hospital Miguel Servet, Pharmacy Service, Zaragoza, Spain.

Background
Chemotherapy regimens go along with a number of varying severity adverse events (AE) which affect the treatment effectiveness due to the need to reduce or delay them.

Purpose
To assess the different chemotherapy regimens toxicity used in first-line treatment of metastatic colorectal cancer (mCRC).

Materials and Methods

11/4/13
Scores:
Retrospective and observational study. It included patients who started a mCRC chemotherapy treatment from October 2011 to June 2012. Toxicity grade was assessed by Common Terminology Criteria for Adverse Events (1-5) version 4.02.

Results
79 patients. Mean age at diagnosis: 66 years old, 54% male. 73.4% of patients were treated with oxaliplatin and they showed: neurotoxicity: 53.4%, 32.8% and 5.2% grades 1, 2, and 3 respectively; nausea and vomiting: 25.9% and 1.7% grades 1 and 2 respectively. 59.5% were treated with 5-fluorouracil and they showed: neutropenia: 8.5%, 19.1%, 12.8% and 21.3% grades 1, 2, 3, and 4 respectively; hand foot syndrome (HFS): 27.7%, 17.0% and 2.1% grades 1, 2, and 3; mucositis: 55.3%, 8.4%, 4.2%, and 2.1% grades 1, 2, and 4; diarrhea: 19.1%, 19.1%, and 6.4% grades 1, 2, and 3; 39.2% were treated with capecitabine: HFS: 22.6%, 9.7%, and 9.7% grades 1, 2, and 3; mucositis: 19.4% and 9.7% grades 1 and 2; diarrhea: 6.1%, 6.5% and 9.7% grades 1, 2, and 3. 55.7% were treated with bevacizumab: hypertension: 2.3%, 13.6%, and 11.4% grades 1, 2, and 3; proteinuria: 58.3% and 16.7% grades 1 and 2; cutaneous rash: 25%, 50%, and 25% grades 1, 2, and 3. 15.2% were treated with cetuximab/panitumumab: paronychia: 58.3% and 16.7% grades 1 and 2; cutaneous rash: 25%, 50%, and 25% grades 1, 2, and 3. Owing to AE treatment was reduced, cancelled or delayed in 31.6%, 25.3%, and 48.1% of the patients respectively.

Conclusions
AE occurred in a high percentage of patients but they were mild-moderate graded and easy handling. It was required to reduce, cancel or delay treatment in a significant patient percentage.

Conflict of interest:
Enter Yes or No: No

Keywords
Toxicity; Metastatic colorectal cancer; Adverse events;

Authors letter
Colorectal cancer is one of the most common neoplasia in western countries. It is the second leading cause of cancer-related deaths after lung cancer in men and breast cancer in women. It is important to determine the incidence and toxicity of the treatments because it is related to the stopping, delay, and reduction of drug dosage and, as a result, the treatment effectiveness decreases. Previously knowing the treatment's toxicity profile and informing the patient may help to establish prior actions in order to minimize its impact.

Score: 200

Remarks all reviewers:
Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Difference between treatments with regard to the need of reducing, cancelling or delaying treatment should be stated
Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.3 Modifications needed: ; ;
Nominee: No

make your results a table: in the present format they are too confusing and unreadable.

BAR14-0570
Analysis of pharmacovigilance reports in pediatric hospital pharmacy

Co-authors
J.D. Jasminka Dragic.1

1Institute for mother and child health care "Dr Vukan Cupic", hospital pharmacy, Belgrade, Serbia.

Background
Spontaneous reporting of adverse drug reactions (ADR) is the responsibility of health professionals because it can increase patient safety.

Purpose
Presentation of ADR reports in nine-year period.

Materials and Methods
Analysis of ADR reports sent to Medicines and Medical Devices Agency of Serbia (ALIMS) from pediatric hospital pharmacy.

Results
The total number of ADR reports in period January 2005 - June 2013 was 45. The most common drug involved was cetirizine (14 reports or 31.1%). The most frequent reactions were chills, rash, urticaria, headache, fever.
The most common outcome was complete recovery - 27 cases (60%). The most severe outcome was hospitalisation with life threatening conditions reported in nine cases (20%). There were no death outcomes.

Analysis of patients by age shows that ADRs in all groups. In group of one month to one year, there were 4 applications (8.9%). In age groups 1-7 years, 7-12, 12-18 and over 18 years number of cases were 9 (20 %), 11(24.4 %), 14 (31.1 %) and 7 (15.6 %), respectively.

Analysis of patients by gender shows that the adverse reactions were more manifested in women (28 cases, 62.2%). When we exclude patients older than 18 years - women from the gynecology department, the number of reports was still higher in females (21 cases, 55.3 %). Naranjo scale was done for all reports and the most frequent rate was possible (score 1-4).

Conclusions
Hospital pharmacists have administrative role in collection of reports, communication within the hospital staff, ALIMS and drug manufacturers. Our results show that special attention must be paid on antibiotics and female gender. For example, after several reports, dosage of ceftriaxone was reduced from 80 to 50 mg/kg in most patients. Analysis of ADR reports give us better insight in pharmacotherapy and opportunity to develop pharmaceutical care skills.

No conflict of interest

Keywords
pharmacovigilance; spontaneous reporting; pediatric hospital pharmacy;

Authors letter
By collecting and analysing adverse drug reaction reports, hospital pharmacist can be involved in pharmacotherapy and patient safety.

Score: 120

Remarks all reviewers:
Santolaya, Rosario: Conclusion warranted
Conflict of interest clear
Rejected Venturini, Francesca: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
1.
Modifications needed: ;

BAR14-0661
Reagent vigilance: Descriptive analysis of the data after four years of practice
Co-authors
S. makram1, I. zakariya1, W. enneffah1, M a el wartiti1, B. mojemmi1, Y. cherrah2, A. Bennana2.
1 mohammed V military teaching hospital - faculty of medicine and pharmacy, rabat, Morocco.
2 Laboratoire de Pharmacologie et de Toxicologie Faculté de Médecine et de Pharmacie de rabat Université Mohammed V Souissi, pharmacie, rabat, Morocco.

Background
In Morocco, reagent vigilance has not so far been introduced into the health care system, yet in the world several cases of declarations and notifications problems with the use of reagents have been reported.

Purpose
The purpose of this study was to report the experience of the Military Hospital of Instruction Mohammed V in Rabat (HMIMV-Rt) of the involvement of the various stakeholders in the management of reagent vigilance.

Materials and Methods
This study, which lasted four years, from July 2009 to July 2013, was conducted in four stages:
- Design Phase: Design and validation of a declaration form prepared by the Pharmacy Pole of HMIMV-Rt
- Phase of Information and awareness raising of different laboratories and departments concerned;
- Phase of distribution, collecting and study the sheet for reagent vigilance;
- Phase of realization and following up on corrective actions decided.

Results
Only 10% of distributed forms were filled during the four years of study, the Oral claim remains predominant. There was an increase in f or claims over the four years of study due to the implementation of preventive and curative measures. 43% of reported cases have concerned medical biology reagents 67.9% of these reports emanated biology laboratories.

Conclusions
The risk relating to the use of reagents for in vitro diagnostic use in our health institutions requires the establishment of a reliable organization. This approach will only be operational by changing individual and collective behavior of staff. The development of a positive and non-punitive approach to error.
absence of judgment in the analysis of information, accountability of all stakeholders and modifying the practices will contribute to improving the notification of reagent vigilance.

No conflict of interest

**Keywords**

Reagent vigilance; IVD Medical Device; hospital;

**Authors letter**

This work allows to improve and to make level the Pharmacy of the HMIMV Rabat

Score: 100

**Remarks all reviewers:**

Santolaya, Rosario: Conclusion NOT warranted
Conflict of interest clear
Rejected

Venturini, Francesca: Conclusion warranted
Conflict of interest clear
 Accepted, but Author modifications

1. Modifications needed: