

# A regional project to reduce adverse drug reactions due to medication errors in hospital

**First published:** 29/05/2014

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5160

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### Study ID

27997

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### DARWIN EU® study

No

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### Study countries

 Italy

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### Study description

**Background:** Medication errors are one of the most common types of medical error. A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. Prescription errors account for 70% of medication errors that could potentially result in adverse drug effects.

**Objectives:** A study has been projected to evaluate the incidence of adverse drug reactions (ADRs) due to medication errors in hospitalized patients before and after educational audits.

**Methods:** All patients, aged  $\geq 18$  years, hospitalized in seven units (three internal medicine and four geriatric) of the University Hospital of Verona during 3 months period (February- April 2013) were included in this study. The project was articulated in 3 phases. In the first one, three monitors registered all ADRs occurred during hospital stay. Two panels of experts (6 physicians, 2 pharmacists and 2 pharmacologists) established, evaluating the available clinic information (e.g. clinical sheet) of all patients and according to the Schumock and Thornton algorithm, if the ADRs were due to medication errors or not, in the case of error they identified the cause. At first the two panels worked separately, at a later stage a data consolidation has been done to have shared data. In the second phase, educational audits directed to health care practitioners have been organized, and tools (e.g., check-list) to reduce the medication errors have been proposed. The third phase, that is similar to the first one and takes account of tools, is in progress.

**Preliminary Results:** Preliminary data of the first phase showed that 1474 have been enrolled in the seven units involved, the analysis has been done for 1009 patients (68%) (median age: 76 years old with  $DS \pm 15,2$ , female: 51%) who gave their informed consent. Three monitors registered 180 ADRs occurred in 1009 hospitalized patients, two panels evaluated 55 ADRs (30% of 180) as avoidable. Further results will be published as available.

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## **Study status**

Finalised

## **Research institutions and networks**

## Institutions

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

 Italy

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**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[giampaolo.velo@univr.it](mailto:giampaolo.velo@univr.it)

### Primary lead investigator

Moretti Ugo

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2011

Actual: 01/01/2011

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**Study start date**

Planned: 04/02/2013

Actual: 04/02/2013

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**Data analysis start date**

Planned: 03/06/2013

Actual: 03/06/2013

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**Date of final study report**

Planned: 30/06/2014

Actual: 30/11/2016

## Sources of funding

- Other

## More details on funding

Italian Medicines Agency

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Other

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**Study topic, other:**

Medication Errors, Disease/Epidemiology study

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this study is to evaluate if educational audits organized in the second phase and directed to health care practitioners have reduced the medication errors due to adverse drug reaction in the third phase.

## Study Design

## **Non-interventional study design**

Cohort

## Population studied

### **Short description of the study population**

All patients, aged  $\geq 18$  years, hospitalized in seven unit (three internal medicine and four geriatric) of the University Hospital of Verona during 3 months period (February- April 2013).

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

3000

## Study design details

### **Outcomes**

All adverse drug reactions registered in all hospitalized patients during the study period and in the involved units

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### **Data analysis plan**

A descriptive analysis will be conducted for all variables. The risk factors for ADRs and medication errors will be identified by studying the effects of age, the

sex, the duration of stay in the department and the severity of ADRs. The results will be expressed in terms of Odds Ratio (OR) with their 95% confidence intervals (95% CI). The level of significance will be estimated at 5%.

## Documents

### Study report

[Drug Saf 2011\\_Pilot Study Med Errors.pdf](#) (1.17 MB)

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown