Effect of Pharmacist Involvement on Patient Reporting of Adverse Drug Reactions: A Multiregional Italian Study

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/6890

EU PAS number

EUPAS5289

Study ID

6890

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Background: Patients may increase spontaneuos reporting system and contribute to the detection of signals. Community pharmacies could have an important role in this context as a service for promoting patient reporting of ADRs. A pilot study was conducted in 2010 in the Veneto Region of Italy to increase the patient reporting through the role of the pharmacist. This project had so good results we decided to extend it to a mullti- regional level. Objectives: to assess the potential impact of an intevention to promote patient reporting in community pharmacies and to compare the characteristics of patients and general practitioners reports of adverse drug reactions (ADRs). Methods: Eight regional centres (Basilicata, Calabria, Campania, Friuli-Venezia Giulia,Lazio, Puglia Bari, Puglia Barletta, Veneto) have been involved in the study. Each pharmacist was asked to select, during the study period, about 240 customers who had received at least one drug and then to offer the spontaneuos reporting form to those who had experienced a suspected ADRs. Patients were asked to complete the ADR report form and either give it back to the pharmacist o send it by fax or email or else to fill in the form online. Preliminary results: in a 3-month period (from October 2013 to March 2014) the study involved 615 pharmacists working in 388 community pharmacies. 115,055 patients (58% female) were interviewed by the pharmacists and 12,185 (10,6%) referred a suspected ADR. The project has collected a total of about 4,000 citizen’s ADR reporting form, corresponding to about 30% of all patients interviewed who had experienced suspected ADRs. After a quality control about 60% of these reports were entered into the Italian Pharmacovigilance Database. A comparison with the reports sent by the general practitioners in the same region and in the same period is in progress. Further results will be published as soon as available.

Study status

Finalised

Research institutions and networks

Institutions

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

Italy

First published: 25/10/2022

Last updated: 13/03/2025

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Department of Experimental Medicine, Section of Pharmacology “Leonardo Donatelli”, Center of Pharmacosurveillance and Pharmacoepidemiology, Faculty of Medicine and Surgery, Second University of Naples (CRF_Campania)

Italy

First published: 28/06/2010

Last updated: 17/06/2011

Institution | **Educational Institution** | **ENCePP partner**

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

PhV Regional Centre of Basilicata Region, PhV Regional Centre of Calabria Region, PhV Regional Centre of Friuli Venezia Giulia Region, PhV Regional Centre of Lazio Region, Centre of Bari, Puglia Region, Centre of Barletta, Puglia Region

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2012

Actual: 01/01/2012

Study start date

Planned: 01/10/2012

Actual: 01/10/2012

Data analysis start date

Planned: 01/09/2013

Actual: 01/09/2013

Date of final study report

Planned: 31/01/2014

Actual: 31/01/2014

Sources of funding

- Other

More details on funding

Italian Medicines Agency

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Promotion and Information of patient reporting

Data collection methods:

Primary data collection

Main study objective:

To assess the potential impact of an intevention to promote patient reporting in community pharmacies and to compare the characteristics of patients and general practitioners reports of adverse drug reactions (ADRs).

Population studied

Short description of the study population

Patients who had received at least one drug

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)

Estimated number of subjects

115000

Study design details

Outcomes

improve patient reporting

Data analysis plan

ADR reports with all mandatory fields were and will be entered into the Italian Pharmacovigilance Database. Drugs were and will be coded using national terminology and following the ATC classification. Drugs reactions were classified usign MedDRA. The characteristics of ADR reports sent by patients were and will be compared with those sent by GPs in the Veneto Region. The Chi- square test was used to compare patient and GPS reports. All calculation were made using Epi Info, a a standard statistical software program developed by the Centers for Disease Control and Prevention, Atlanta, US.

Documents

Study, other information

leone_drugsafety.pdf(85.28 KB)

Data management

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No