

EREMI - Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions

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General	
Identification	
Detailed name	Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions
Sign or acronym	EREMI
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	MMS/MTE/AR1411279
General Aspects	
Medical area	Pediatrics
Pathology (details)	Adverse drug reactions
Health determinants	Iatrogenic Medicine
Keywords	drug, ADEs, Adverse drug episodes, adverse effect, market authorisation, prescription, Hospitalisation, MA, child, adolescent
Scientific investigator(s) (Contact)	
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Unit	Clinical Investigation Centre Hospices Civils de Lyon /Inserm EPICIME (Epidemiology, Pharmacology, Clinical Research and Medical information, Mother and Child) UMR 5558/CNRS
Organization	Hospices Civils de Lyon (HCL)

Collaborations

Participation in projects, networks and consortia	Yes
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Details	CIC Pédiatrique - Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / CIC pédiatrique - Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)
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Funding

Funding status	Public
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Details	ANSM Financing 2012 - Axis 2: Analysis of off-label drug use
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Governance of the database

Sponsor(s) or organisation(s) responsible	Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL)
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Organisation status	Public
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Sponsor(s) or organisation(s) responsible	Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)
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Organisation status	Public
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Presence of scientific or steering committees	Yes
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Additional contact

Name of the contact	Nguyen
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Unit

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Unit

UMR5558/LBBE

Organization

Hospices Civils de Lyon/UCBL

Main features

Type of database

Type of database

Study databases

Study databases (details)

Cohort study

Database recruitment is carried out by an intermediary

A selection of health institutions and services
A population file

Database recruitment is made on the basis of:

Medication(s) taken

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

Automated prospective extraction of drug administrations from the HCL Hospital Information System / Active and spontaneous detection of adverse drug events

Database objective

Main objective

To compare the probability of occurrence of an adverse drug reaction (ADR) after a licensed

prescription drug versus the probability of occurrence of an ADR after prescribing a drug off-label or unlicensed in patients aged 0-15 years hospitalized at least 3 days

Secondary objectives:

? Compare the proportion of pediatrics inpatients presenting at least one ADR among inpatients with at least one off-labels or unlicensed prescription drug with the proportion of inpatients presenting at least one ADR among inpatients with all licensed prescription drugs

? To describe, in terms of marketing autorisation and indications, the medicinal products prescribed by paediatric age group.

? Identify the factors influencing the risk of developing ADRs after prescribing a drug

? To estimate the seriousness and avoidability of ADRs

Inclusion criteria	Children from 0 to 15 years old [0 ; 15[(including term and preterm newborn infants). Hospitalised for at least 3 days. Receiving at least one medication
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Pathology	Y40-Y59 - Drugs, medicaments and biological substances causing adverse effects in therapeutic use
Gender	Male Woman
Geography area	Local
Detail of the geography area	Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)
Data collection	
Dates	
Date of first collection (YYYY or	2013

MM/YYYY)

Date of last collection (YYYY or MM/YYYY)	2016
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Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
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Details of the number of individuals	6227
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
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Clinical data (detail)	Direct physical measures Medical registration
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Details of collected clinical data	Nature and clinical context of ADEs
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Declarative data (detail)	Face to face interview Phone interview
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Details of collected declarative data	Spontaneous reporting of ADEs by medical teams / Aid to reporting ADEs actively detected by the EREMI team
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Biological data (detail)	Creatinine level
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Administrative data (detail)	Admission dates, Duration of stay. Extractions from the hospital information system (prescriptions, doses, anthropomorphic and biological data)
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
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Care consumption (detail)	Hospitalization Medicines consumption
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Procedures

Data collection method	During hospitalisation
Quality procedure(s) used	Methodology: HCL Paediatric Clinical Investigation Centre; Biostatistics: Biostatistics department of HCL/UMR CNRS 5558; Management of the database: ClinInfo, Lyon
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by contact with the referring doctor Monitoring by crossing with a medical-administrative database
Details on monitoring of participants	Duration of monitoring of patients who have had an ADE after discharge: 1 month
Links to administrative sources	Yes
Linked administrative sources (detail)	PMSI
Promotion and access	
Promotion	
Link to the document	http://adc.bmj.com/content/99/Suppl_2/A62.2.abstr.act?sid=0943db08-e27a-4da7-bb7a-909ec1a19723; http://www.sciencedirect.com/science/article/pii/S0929693X14719591; http://www.sciencedirect.com/science/article/pii/S0929693X1472130X; http://www.sciencedirect.com/science/article/pii/S0929693X14721311; http://www.sciencedirect.com/science/article/pii/S0929693X14722432
Other information	NCT02852590, protocol available on clinicaltrial.gov (https://clinicaltrials.gov/ct2/show/NCT02852590?term=EREMI&rank=1)
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Request from M Behrouz.Kassai (behrouz.kassai-koupai@chu-lyon.fr or Mrs Kim An Nguyen: kim-an.nguyen@chu-lyon.fr
Access to aggregated data	Access on specific project only

Access to individual data

Access on specific project only