Prevalence and clinical impact of the label ‘beta-lactam allergy’ in APHP hospitals: a cross-sectional study based on health data from a single day BETALL

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Study Planned

Administrative details

EU PAS number

EUPAS1000000897

Study ID

1000000897

DARWIN EU® study

No

Study countries

France

Study description

Beta-lactam allergy is the most frequently reported drug hypersensitivity. Yet its true prevalence is largely overestimated: although 5–15% of adults declare penicillin allergy, fewer than 10% are confirmed after testing. Incorrect allergy labels lead to inappropriate antibiotic choices, longer hospital stays, higher risk of treatment failure, C. difficile infection, and antimicrobial resistance. Improving documentation accuracy is therefore a key public health priority.
This study aims to (1) estimate the prevalence of documented beta-lactam allergy within AP-HP; (2) assess the proportion of confirmed allergies; (3) evaluate the quality of EHR documentation; and (4) analyse the impact of allergy labels on antibiotic prescribing.
We will conduct a one-day cross-sectional study using the AP-HP Health Data Warehouse. All adults (≥18 years) hospitalised or seen on 14 December 2022 in ORBIS-enabled hospitals will be included, except psychiatry, rehabilitation, emergency, and critical care units. Allergy information will be identified through structured EHR fields, PMSI coding, and text-mining of clinical notes. Descriptive analyses and bootstrap confidence intervals will estimate prevalence, with subgroup analyses by hospital, specialty, age, and sex.
This study will provide the first large-scale estimate of beta-lactam allergy labelling at AP-HP, highlight gaps in documentation and confirmation, and support interventions to improve antimicrobial stewardship and patient safety.

Study status

Planned

Research institutions and networks

Institutions

Centre de pharmaco-épidémiologie (Paris Pharmacoepidemiology Centre), Assistance Publique, Hôpitaux de Paris

France

First published: 14/11/2011

Last updated: 22/07/2015

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/07/2024

Study start date
Planned: 14/12/2022

Data analysis start date
Planned: 20/09/2025

Date of final study report
Planned: 01/02/2027

Sources of funding

- Other

More details on funding

Government body: DGOS

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:

Other

Study topic, other:

Beta-lactam drug hypersensitivity labelling

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Retrospective cross-sectional study using AP-HP EDS data to estimate the prevalence of β-lactam allergy labelling on 14/12/2022 in adults receiving care. Inclusion of ORBIS-managed patients; exclusion of emergency, ICU, psychiatry, SSR, and protected adults.

Main study objective:

Estimate the prevalence of β-lactam allergy labelling among adults receiving care at AP-HP on 14/12/2022 using EDS data

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

The study population includes all adult patients (≥18 years old) who had a consultation or hospitalization within AP-HP on the index date of December 14, 2022, within hospital departments using the ORBIS information system. This includes outpatient visits, day hospitalizations (HDJ), week hospitalizations (HDS), and conventional inpatient stays (MCO). This population corresponds to the full denominator used to estimate the prevalence of β-lactam allergy labelling within AP-HP. Among these patients, those carrying a β-lactam allergy label will form the subpopulation used for secondary analyses.

Inclusion criteria

• Patients aged 18 years or older.

• Patients who consulted or were hospitalized in AP-HP services using ORBIS on 14/12/2022 (consultations, HDJ, HDS, or conventional hospitalization).

Exclusion criteria :

• Patients managed in Emergency Departments (SAU) or Short-Stay Units (UHCD).

• Patients in intensive care or critical care units.

• Patients in post-acute/rehabilitation units (SSR).

• Patients hospitalized in psychiatry departments.

• Patients with major neurocognitive disorders.

• Patients under legal protection (safeguard of justice).

• Patients covered by CMU or AME.

Scope : All eligible patients from all AP-HP hospitals present in the EDS are included. Linked stays around the index date are considered to ensure complete extraction of relevant clinical documents.

Age groups

- **Adult and elderly population (≥18 years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

33.150

Study design details

Setting

The study is conducted within the AP-HP hospital network, using data from the Entrepôt de Données de Santé (EDS AP-HP). The source population includes all patients aged 18 years or older who had at least one encounter (inpatient or outpatient) within any AP-HP hospital on 14 December 2022, regardless of medical specialty. Care settings include general medicine, surgery, emergency departments, and psychiatry.

From this source population, the study identifies patients with at least one mention of suspected or confirmed β-lactam allergy ("β-lactam allergy labelling") extracted from structured and unstructured EHR components (diagnosis codes, medical notes, prescriptions, documented drug allergy lists).

Selection criteria follow the protocol specifications:

• Inclusion criteria:

- Adults ≥18 years old;

- At least one contact with an AP-HP facility on 14/12/2022;

- Availability of EHR data in the EDS;
- For analyses restricted to labelled patients: presence of a β-lactam allergy mention.

• Exclusion criteria:
- Patients who opted out of secondary use of their health data;
- Patients with invalid pseudonymisation keys;
- Records lacking essential demographic data.

The study period is fixed and cross-sectional: exposure and outcomes are assessed at a single index date (14 December 2022), with retrospective retrieval of historical EHR information (e.g., prior hospitalisations, prior prescriptions) when relevant for descriptive stratifications. No intervention, treatment arm, or comparator group is defined, as the study aims solely to characterise β-lactam allergy labelling prevalence and the epidemiological profile of labelled patients.

This setting ensures exhaustive coverage of all AP-HP patients on a predefined day, enabling a robust estimation of β-lactam allergy labelling prevalence at the hospital-network level.

Outcomes

Primary Outcome

The primary outcome is the prevalence of β-lactam allergy labelling among all adult patients (≥18 years) who had at least one encounter within an AP-HP care unit (outpatient visit, day hospital, emergency care, short-stay or conventional hospitalization) on the index date 14 December 2022.

A patient will be considered labelled as “β-lactam allergic” if at least one explicit mention of suspected or confirmed β-lactam allergy is identified in the electronic health record, using:
- structured data (Orbis allergy list, diagnosis codes),
- unstructured data processed by Natural Language Processing (NLP),

- PMSI (ICD-10 allergy-related codes or mentions).

The prevalence will be computed as:

Prevalence = (Number of patients labelled as β-lactam allergic)/(Total number of adult patients seen at AP-HP on 14/12/2022)

This prevalence estimation includes all labelled patients, regardless of whether confirmatory allergy testing has been performed.

Data analysis plan

The primary analysis will consist of estimating the prevalence of β-lactam allergy labelling, expressed as a percentage with 95% bootstrap confidence intervals (resampling at the patient level).

The allergy status will be classified using all available EHR information:

1. Confirmed allergy: at least one positive β-lactam allergy test documented in the medical record.
2. Ruled-out allergy: at least one negative allergy test, indicating the label should no longer apply.
3. Label without testing: mention of β-lactam allergy with no confirmatory test found.

For the primary prevalence analysis, all patients with any allergy label (with or without testing) will contribute to the numerator. Confirmatory test results will be used in secondary descriptive analyses to characterise mislabelling (e.g., proportion of ruled-out allergies still labelled in the EHR).

Stratified analyses will describe prevalence by sex, age group, hospital type, and care sector. Sensitivity analyses may exclude patients with contradictory or ambiguous information.

No modelling is required, as the study aims at descriptive epidemiology.

Internal validity will rely on reproducible extraction rules, NLP quality checks, and robustness analyses across data sources.

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 source(s), other

The datasource is the APHP Clinical Data Warehouse

Data sources (types)

Electronic healthcare records (EHR)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction