

# Reducing antibiotic use in primary care: a pharmacist-led educational and audit & feedback strategy

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<b>Registration date</b> 11/12/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/07/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to improve how general practitioners (GPs) prescribe antibiotics by providing them with educational support and feedback. The goal is to ensure antibiotics are used correctly to combat resistance and improve patient care.

### Who can participate?

All general practitioners (GPs) working in primary health care centers in three Spanish Health Care Districts: Mallorca (Balearic Islands), Paterna (Valencia), and Tarragona-Reus (Catalonia) will participate. A total of 112 GPs are required for the study.

### What does the study involve?

GPs will receive personalized feedback on their antibiotic prescribing habits, including information on selection, dosage, duration, and the conditions treated. Those who request additional help or are in the highest prescribing quartile will get one-on-one support from a study pharmacist. This includes setting goals, creating action plans, and discussing specific cases. Participants will also have access to an online educational course.

### What are the possible benefits and risks of participating?

The main benefit is improved antibiotic prescribing practices, which can lead to better patient outcomes and reduced antibiotic resistance. There are no significant risks for the GPs participating in this study.

### Where is the study run from?

The study is conducted in three Spanish Health Care Districts: Mallorca (Balearic Islands), Paterna (Valencia), and Tarragona-Reus (Catalonia).

### When is the study starting and how long is it expected to run for?

January 2023 to December 2026

Who is funding the study?

The study is funded by the Carlos III Institute of Health (PI22/01742) (Spain)

Who is the main contact?

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## Contact information

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Public, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

# Study information

## Scientific Title

A pharmacist-led educational intervention and audit & feedback approach to reduce antibiotic prescriptions in primary care

## Acronym

AFA study

## Study objectives

Current study hypothesis as of 06/01/2025:

An Audit & Feedback intervention targeting general practitioners (GP), which includes individualized graphical data on antibiotic prescriptions (covering antibiotic selection, dosages, treatment duration, and associated conditions) combined with a pharmacist-led educational intervention consisting of an individualized, face-to-face session with a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component, reduces antibiotic prescriptions by at least 1 point in the ratio of total antibiotic prescriptions per 100 visits, for individuals aged 14 years and older.

Previous study hypothesis:

An Audit & Feedback intervention targeting general practitioners (GP), which includes individualized graphical data on antibiotic prescriptions (covering antibiotic selection, dosages, treatment duration, and associated conditions) combined with a pharmacist-led educational intervention consisting of an individualized, face-to-face session with a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component, reduces antibiotic prescriptions by at least 4 daily doses per 1,000 inhabitants per day (DHD) in individuals over 14 years of age.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 14/07/2023, Balearic Islands Ethics Committee (c/Calçat, 2A, 2n, Palma, 07011, Spain; +34 971177378; ceic\_ib@caib.es), ref: IB 5219/23 PI

## Study design

Multicenter parallel randomized clinical trial

## Primary study design

Interventional

## Study type(s)

Efficacy

## Health condition(s) or problem(s) studied

Reduction of antibiotic prescription in primary care

## Interventions

The method of randomization is simple random sampling.

General practitioners (GPs) in the intervention arm will receive individualized monthly information about their antibiotic prescription (incorporating graphical data, including antibiotic selection, dosages, treatment duration, and associated conditions), combined with an individualized, face-to-face intervention by a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component.

GPs in the control group will receive an intervention to reduce potentially inappropriate medication use (benzodiazepines, proton pump inhibitors and antipsychotics in patients with dementia) in patients over 65 years old.

The follow-up of the intervention is 12 months.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Current primary outcome measure as of 06/01/2025:

The efficacy of the interventions on the prescription of antibiotics in the primary care area, measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up. The primary outcome will be measured as the total number of antibiotic prescriptions per 100 visits.

Previous primary outcome measure:

The efficacy of the interventions on the prescription of antibiotics in the primary care area, measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up

## **Key secondary outcome(s))**

Current secondary outcome measures as of 07/05/2025:

1. Percentage of patients who start antibiotic treatment measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up.
2. Antibiotic prescription according to therapeutic group of antibiotics measured using number of antibiotic prescriptions according to therapeutic group (beta-lactams, glycopeptides, macrolides, aminoglycosides, tetracyclines, quinolones and fluoroquinolones, sulfonamides, lincosamides, oxazolidinones, polymyxins, rifamycins, nitroimidazoles, nitrofurans, fosfomycin) extracted from the e-prescription databases of each health district at 12-month follow-up.
3. Antibiotic prescription according to prescription pathology measured using the number of antibiotic prescriptions and their associated pathology (lower and upper respiratory infections, lower and upper urinary tract infections, sexually transmitted infections, skin and soft tissue infections, oral and odontogenic infections) at 12-month follow-up.
4. Antibiotic prescription according to gender measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district, considering the gender of the GP and gender of the patient at 12-month follow-up.
5. The reach, engagement, adoption, fidelity and maintenance of the intervention. Reach will be defined as the percentage of participating GPs relative to the total number of eligible GPs. Engagement will measure the degree of active involvement in the intervention, including use of the feedback reports, participation in pharmacist-led sessions, and integration of recommendations into clinical practice. Adoption will be measured at the organizational level as the percentage of healthcare management units that have agreed to implement the

intervention. Fidelity to the intervention will be assessed through audits of adherence to the planned feedback delivery process. This includes consistency in the timing and content of reports, implementation of pharmacist consultations, and completion of online training modules. Maintenance of the intervention will be assessed at 6 and 12 months post-intervention, focusing on the degree to which the intervention becomes institutionalized within the healthcare system.

Previous secondary outcome measures:

1. Percentage of patients who start antibiotic treatment measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up.
2. Antibiotic prescription according to therapeutic group of antibiotics measured using number of antibiotic prescriptions according to therapeutic group (beta-lactams, glycopeptides, macrolides, aminoglycosides, tetracyclines, quinolones and fluoroquinolones, sulfonamides, lincosamides, oxazolidinones, polymyxins, rifamycins, nitroimidazoles, nitrofurans, fosfomycin) extracted from the e-prescription databases of each health district at 12-month follow-up.
3. Antibiotic prescription according to prescription pathology measured using the number of antibiotic prescriptions and their associated pathology (lower and upper respiratory infections, lower and upper urinary tract infections, sexually transmitted infections, skin and soft tissue infections, oral and odontogenic infections) at 12-month follow-up.
4. Antibiotic prescription according to gender measured using the number of antibiotic prescriptions extracted from the e-prescription databases of each health district, considering the gender of the GP and gender of the patient at 12-month follow-up.
5. The reach of the intervention as well as the fidelity of the intervention execution. The reach of the intervention will be measured using the percentage of patients assigned to GPs, with any antibiotic prescription and eligible to receive the intervention at 12 months follow-up. The fidelity will be measured using a comprehensive record with a detailed description of the execution process and any adaptations made in each intervention, as well as the strategies they comprise at the 12-month follow-up.

**Completion date**

12/12/2026

## **Eligibility**

**Key inclusion criteria**

All GPs with assigned patients in their primary care health center will be included

**Participant type(s)**

Health professional

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/05/2025

**Date of final enrolment**

31/12/2025

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

**Balearic Islands Health Service (IB-Salut)**

Carrer de l'Escola Graduada, 3, Centre

Palma

Spain

07002

**Study participating centre**

**Paterna Health District (Conselleria de Salut Universal; Arnau de Vilanova-Llíria district)**

Paterna

Spain

46980

**Study participating centre**

**Tarragona-Reus Health district (Institut Català de la Salut; Tarragona-Reus district)**

Tarragona

Spain

43480

## **Sponsor information**

**Organisation**

Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Instituto de Salud Carlos III

**Alternative Name(s)**

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCI), ISCI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		19/07/2025	21/07/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes