

Spanish Action Plan on Antibiotic Resistance

PROA Team Certification Standard

Hospital



Spanish Agency for Medicines and Medical Devices (AEMPS)

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GLOSSARY OF TERMS

A/C	Amoxicillin/Clavulanic acid
AB	Antibiotics
AEMPS	Spanish Agency for Medicines and M
AMOX	Amoxicillin
AMP	Ampicillin
ATC	Anatomical Therapeutic Chemical
В	Bacteria
CD	Clindamycin
CIP	Ciprofloxacin
CRO	Ceftriaxone
СТХ	Cefotaxime
CXM	Cefuroxime
DDD	Defined Daily Dose
DNI	National Identity Card
DOT	Days Of Therapy
ECDC	European Centre for Disease Prever
ECOFF	Epidemiological Cut-Off value
EUCAST	European Committee on Antimicrobi
ERI	Erythromycin
ESBL	Extended-spectrum beta-lactamases
FD	Nitrofurantoin
FOS	Fosfomycin
FUS	Fusidic Acid
GM	Gentamicin
GINF	Guide for the assessment of Inclusio
HIVAT	Home Intravenous Antimicrobial The
I.	Susceptible with increased exposure
ICU	Intensive care unit
IDIVAL	Marqués de Valdecilla Research Insti
	A/C AB AEMPS AMOX AMP ATC B CD CIP CRO CTX DDD DDT ECOCFF EUCAST FD FDS FUS GM GINF HIVAT I ICU IDIVAL

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GLOSSARY OF TERMS

INGESA	National Institute for Health Management
ISCIII	Carlos III Health Institute
MIC	Minimum inhibitory concentration
MR	Multidrug-resistant
MRB	Multidrug-resistant Bacteria
MRSA	Methicillin-resistant Staphylococcus aureus
MSSA	Methicillin-sensitive Staphylococcus aureus
MUP	Mupirocin
N/A	Not Applicable
OXA	Oxacillin
PEN	Penicillin
PK/PD	Pharmacokinetics/Pharmacodynamics
PRAN	Spanish National Action Plan on AMR
PROA	Antimicrobial Stewardship Program
R	Resistant
REvalMed	SNS Medicines Evaluation Network
S	Sensitive
SNS	Spanish National Health System
SXT	Trimethoprim-sulfamethoxazole or co-trimoxazole
TET	Tetracycline
ТОВ	Tobramycin

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Devices	SEMFYC. Spanish Society of Family and Community Medicine					
AEPAP. Spanish Association of Primary Care Paediatrics	SEMG. Spanish Society of General and Family Physicians					
PRAN. Spanish National Action Plan on AMR	SEPEAP Spanish Society of Out-Of-Hospital Paediatrics and					
SEIMC. Spanish Society of Infectious Diseases and Clinical Microbiology	Primary Care					
SEFAP. Sociedad Española de Farmacéuticos de Atención						

Primaria **SEFH.** Spanish Society of Hospital Pharmacists



LETTER FROM THE DIRECTOR

It is an honour to have the opportunity to present one of the most ambitious projects to date of the Spanish National Action Plan on AMR (PRAN) in the area of human health: the Certification Standards for Antimicrobial Stewardship Programs (PROA).

Spain's commitment to reducing bacterial resistance has been notable since the PRAN was created in 2014. In 2021, almost 100% of hospitals claimed to have some PROA initiative in place, as is the case at the community level. We are proud to see the interest of health professionals and their willingness to get involved in this global problem.

Given the importance of these programmes, it is necessary that the characteristics and activities to be implemented by PROA teams, while adapted to local circumstances, have, as a starting point, a common basis that is defined and sufficiently homogeneous at the national level. In order to achieve this objective, and taking into account the multidisciplinary nature of the PROA teams, PRAN has teamed up with healthcare professionals from different fields and specialities in the development of the PROA Certification Standards for community and hospital teams.

Both the hospital and community PROA Team Certification Standards adopt the characteristics and optimisation strategies specific to each setting, but the effort goes further, as the link between hospital and community settings has been established. In this way, healthcare coordination takes on special relevance, as it leads to improved communication and multidisciplinary collaboration between PROA teams from different healthcare levels, as well as setting common objectives, protocols and procedures.

As with any lever for change, the implementation of the Standards is a challenge for both regional health ministries and the health professionals involved in these programmes. In this regard, I would like to highlight the National Health System's commitment to achieving quality benchmarks, for which the provision of technical and human resources is essential.

I must add the great value of the consensus achieved thanks to the joint work of the authors of both documents who, with a global perspective of patients' needs, have agreed on actions and measures aimed at guaranteeing the coordination and continuity of healthcare; so important in dealing with infections caused by multidrug-resistant bacteria.

Furthermore, the support of all the autonomous communities that endorse both certification standards and the approval by the Interterritorial Council of the National Health System provides these programmes with the institutional framework that had been demanded. To guarantee this, PRAN provides the PROA teams with **CertificaPROA**, a tool that allows for self-certification and certification to give these quality programmes the recognition they deserve.

On behalf of PRAN and the Spanish Agency for Medicines and Medical Devices (AEMPS), I would like to express my sincere thanks to each of the individuals and institutions that have participated in and support this project.

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María Jesús Lamas Díaz Director, Spanish Agency for Medicines and Medical Devices



INTRODUCTION

The complexity of infectious diseases and the increase in resistance make it essential to set up Antimicrobial Stewardship Programs (PROA) in hospital and community settings. This programme aims to optimise antibiotic prescribing, ensure optimal clinical outcomes, minimise the adverse effects of antibiotic use, control the development of resistance and ensure the use of cost-effective treatments¹.

From the outset, PROAs have been integrated into the National Antibiotic Resistance Plan (PRAN) strategy and a national, regional and institutional regulatory framework was created in 2017 to enable PROAs to be successfully developed in different health settings¹. In order for PROAs to be implemented, it was necessary to establish a standard that would serve as a working guide and define the best practices and prerequisites to be met by centres with a PROA in place.

Furthermore, in order to achieve maximum recognition, institutional support and homogeneous implementation at the hospital and community level throughout the country, as well as acceptance of the programme by all professionals, it was essential for the centres to be certified. To this end, the PRAN has developed not only the Standards, but also a tool that gives recognition to best practices carried out in the hospital or primary healthcare centres: **CertificaPROA**.

Development of the PROA Certification Standards

A quality survey of PRAN partners in 2020 revealed that 94% of respondents confirmed that they had some PROA initiative in hospitals. The community level showed a similar percentage, with 93.4% of respondents stating that they had a PROA initiative in their health area². The PROAs are a reality for most centres thanks to the work of health professionals and the efforts of the administrations. However, the different level of implementation and the geographical variety reflect the need to standardise the work of PROA teams. It is within this framework that the PROA Standards are born, as the necessary tool to promote implementation, adapted to local circumstances, but methodologically homogeneous throughout Spain. Together with CertificaPROA, it will allow comparison and identification of centres according to their degree of commitment to the good use of antimicrobials³.

To start developing the hospital PROA certification standard, the document published by SEIMC and SEFH 'Standards for the certification of hospital PROAs'⁴, and for the community

¹Spanish Agency for Medicines and Medical Devices (AEMPS). Spanish National Action Plan on AMR (PRAN). Antibiotic use optimisation programmes (PROA). Madrid: AEMPS; 2017.

²Spanish Agency for Medicines and Medical Devices (AEMPS). Spanish National Action Plan on AMR (PRAN). Strategic and Action Plan to Reduce the Risk of Selection and Spread of Antibiotic Resistance 2022-2024. Madrid: AEMPS; 2022.

³J. Rodríguez-Baño et al / Enferm Infecc Microbiol Clin. 2012;30(1):22.e1–22.e23.

level, a proposal was developed in which AEPap, SEMG, SEFAP, SEMERGEN, SEMFYC, SEPEAP, SEIMC and PRAN participated. Both documents were submitted for consultation to the Autonomous Communities and the PRAN.

The PRAN coordinated and participated in the revision exercise, with the aim of homogenising and harmonising the structure of both documents, ensuring continuity of healthcare by orchestrating the agreement between the scientific societies involved, which came from different healthcare settings, reinforcing the evidence of the benchmarks, as they are fundamental to the process of self-certification and certification of PROAs, and including the perspective of the autonomous communities.

This work resulted in a first document which was subsequently reviewed by multidisciplinary groups of experts from the community and hospital sectors with recognised experience in the implementation of PROA.

In parallel, PRAN has been working on the design and development of an electronic tool (CertificaPROA) with the aim of facilitating the process of self-certification and certification of PROAs.

Finally, on 18 May 2022, the benchmarks for the Standards for the certification of hospital and community PROA teams were approved by the representatives of the autonomous communities in the PRAN Coordinating Committee and, on 19 December 2022, by the Interterritorial Council of the National Health System.

⁴Standards for the certification of SEIMC-SEFH hospital PROAs. 2016.



STRUCTURE OF PROA TEAM **CERTIFICATION**

The Hospital PROA Team Certification Standard consists of 50 benchmarks. Each benchmark defines the prerequisite to be met for the implementation of PROAs. The prerequisites are classified according to the degree of development of the desired PROA, the associated prerequisite can be at the basic, advanced or excellent level:

- Basic: a measure that should be implemented in all hospitals.
- Advanced: recommended measure in centres with a more mature implementation of the programmes.
- Excellent: optimal measure, which will generally be applied in referral hospitals or health areas.

They are further classified as mandatory or non-mandatory.

Given the complexity of implementing some of the benchmarks, some of them have been broken down into different levels of compliance and, in some instances, even into three levels of compliance (basic, advanced and excellent) in order to recognise and facilitate their achievement.

This results in different combinations giving a total of 71 prerequisites:

	Mandatory	Non-mandatory	Total
Basic 🔺	21	3	24
Advanced 🛦 🛦	17	8	25
Excellent	8	14	22
Total			71

The benchmarks are structured in the document as follows:



BM21. Development of an ongoing training programme on antibiotic use for hospital units and services involved in the prevention, diagnosis and treatment

Development of an annual comprehensive training programme to be presented to the main services involved in the prevention, diagnosis and treatment of patients with infectious

A request will be issued for the plan of the comprehensive training programme and attendan-

Development of a training programme adapted to the specific characteristics of the department/unit to be delivered to the departments identified by the PROA team as critical in antibiotic use. At least one specific programme per year is recommended.

ted to the service/unit identified as critical in the antibiotic use and the attendance records in order

STRUCTURE OF PROA TEAM CERTIFICATION

The benchmarks are distributed into the following typologies:

Typology I. Organisational aspects. It includes those benchmarks that describe organisational and functional aspects, as well as the development of a framework document where the strategies that best fit the centre's situation are selected. The PROA teams report to the Infections and Antibiotics Commission, and consist of a multidisciplinary team responsible for the design, development, implementation, monitoring and dissemination of programme results.

Typology II. Institutionalisation. All those benchmarks that imply a commitment of centre management to the PROA are included. The PROAs are cross-sectional quality programmes that extend throughout the centre. This institutional character is essential, both to facilitate the acceptance of the programme by all professionals and to secure the necessary resources, as it normalises the activities of the team responsible for the programme, considering them as important as any other healthcare activity.

Typology III. Human and technical resources. It includes the minimum human and technical resources to be made available in order to implement the programme. For the proper implementation of the PROA, planning and coordination of the human resources available to implement the proposed actions is needed³. Depending on the desired degree of excellence, it may be necessary to include staff specifically dedicated to the programme. Technical resources have been set up according to the indicators (process, result) to be monitored.

Typology IV. Indicators. It includes minimum indicators per certification prerequisite, reporting and specific targets. The described indicators detail the frequency of measurements and, depending on the strategic relevance of the indicator and the desired degree of excellence, some of the data will be individualised³. Monitoring of different types of indicators is essential to be able to assess the situation of the centre, prioritise needs, design activities and assess their impact in an appropriate way³. In addition, it is important to regularly disseminate the results among the centre's professionals in clinical sessions or via the centre's website, and to the medical board as part of the annual monitoring report.

Typology V. Educational interventions. It includes training for professionals on antibiotic use. Training activities are one of the key interventions of PROAs with the aim of improving antibiotic prescribing habits and assessing the quality of prescribing. These activities are aimed at all healthcare professionals involved in the prevention, diagnosis and treatment of infections, including residents-in-training.

Typology VI. Non-tax measures to help prescription. It encompasses all those measures that help decision making: development of protocols and clinical guides, training campaigns, guality assessments, etc.

Typology VII. Measures to promote coordination between healthcare levels and continuity of healthcare. This typology is common in the community PROA team certification standard. It includes specific agreed measures for coordination and communication between hospital and community ³J. Rodríguez-Baño et al / Enferm Infecc Microbiol Clin. 2012;30(1):22.e1–22.e23.

PROA teams. Having common objectives, liaison professionals, agreed processes (guides and protocols) and vertical information systems that help to improve patient monitoring are undoubtedly actions that will favour coordination and continuity of healthcare⁵.

How to obtain the excellence rating?



⁵R Terraza et al/ Gac Sanit vol 20 no 6 Barcelona Nov/Dec 2006

SELF-CERTIFICATION AND CERTIFICATION PROCESS

The process consists of two phases:

1. Self-certification: Statement of undertaking made by the applicant centre substantiating compliance with benchmarks in the absence of certification. To corroborate that the information is accurate, regional administrations will request evidence of the so-called "strategic requirements", which have been identified with a key in the PROA team certification standards. This self-certification will be valid until the certification is completed.

The process involves the following steps:

- Completion of a questionnaire by the applicant centre. Based on the responses, the tool automatically assigns the relevant excellence rating.
- Submission of documentary evidence to substantiate compliance with strategic requirements (identified throughout the document with a keys symbol (>) of the assigned category and below. For example: if the advanced category is assigned, evidence must be provided to justify the fulfilment of the prerequisites of both the basic and advanced levels.
- Review of the documents by a PROA regional representative.
- 2. Certification of PROA teams: audit process coordinated by the Inspection Coordination Commission, under the General Directorate of Professional Organisation of the Ministry of Health. In order to obtain certification, the applicant centre must attach all other documents with supporting evidence for both the category authorised by the regional representative and any lower categories.

Self-certified and certified centres will be published on an interactive map on the website (https://resistenciaantibioticos.es), thus conferring a distinction beyond the recognition itself.

HOSPITAL PROA TEAM CERTIFICATION STANDARD





BM1. The hospital sets and appoints a PROA team under the Infections and Antibiotics Commission.

Clarifications N/A

Benchmark level Basic mandatory

Evidence

A request will be issued for the minutes of the Infections and Antibiotics Commission meeting in which the PROA team is constituted and approved.

BM2. The PROA team at least consists of clinical experts in infectious diseases, hospital pharmacy and microbiology.

Clarifications

The PROA core team should be represented by a clinician with expertise in infectious diseases, usually the coordinator, a hospital pharmacist and a microbiologist. To enrich the core team, professionals can be brought on board from those listed in the PRAN document: 'Antibiotic use optimisation programmes (PROA)'.

Benchmark level Basic mandatory

Evidence

A request will be issued for the professional category of each member of the PROA team.

BM3. Definition of the roles of all PROA team members. A O

- Clarifications N/A
- Benchmark level **Basic mandatory**

Evidence

A request will be issued for the list of functions of the members of the PROA team.

BM4. PROA Framework Document. A O

Clarifications

A PROA Framework Document is to be prepared. It should include the following points:

- Assessment of the local situation.
- Programme design adapted to the centre.
- be provided, together with the representatives for the different PROA activities and a description of the roles of all participants.
- resistance and achievement of clinical objectives.
- · Planning interventions to optimise antimicrobial prescribing.
- Strategy to disseminate the PROA among all the professionals involved in the centre so that they are aware of its mission and objectives.
- Benchmark level Basic mandatory

Evidence

A request will be issued for the PROA Framework Document signed by the medical director to substantiate that it includes the points detailed in the benchmark.

List of human resources needed for developing the PROA. A list of PROA members should

· Definition of overall PROA objectives related to antimicrobial use, control of bacterial





BM5. Organisation and recording of PROA team's activities: meetings, taking minutes and follow-up of decisions. $\land \circ$

Clarifications

The frequency of the meetings of the PROA team depends on the organisation of each centre, with a minimum of 6 meetings per year recommended.

Benchmark level Basic mandatory

Evidence

A request will be issued to the PROA team for the minutes of the meetings held and the follow-up of the decisions. They will be included in the annual monitoring report.





BM6. Explicit support from the medical board and the Infections and Antibiotics Commission.

Clarifications

The aim of this benchmark is that there is a clear commitment from centre management. Management is responsible for implementing the activities foreseen in the Framework Programme, monitoring and analysing PROA indicators and disseminating the results.

Benchmark level

Basic mandatory

Evidence

A request will be issued for the following:

- Certificate (Annex I) attesting that the medical board of the centre is responsible for promoting the activities set out in the Framework Programme, for indicator monitoring and analysis and for disseminating results.
- The minutes of the Infections and Antibiotics Commission to document the constitution and approval of the centre's PROA.

BM7. Inclusion of the PROA in the hospital's strategic objectives.

Clarifications

To demonstrate management commitment to the PROA, it must be included in the hospital's strategic objectives.

Benchmark level

Advanced mandatory

Evidence

The hospital's strategic objectives will be examined for proof that the PROA is included among them.

BM8. Inclusion of incentives linked to PROA objectives for medical, critical and surgical services related to PROA activities.

Clarifications

The aim is to encourage the engagement of professionals with the programme.

Benchmark level Excellent mandatory

Evidence

Documentation certifying that the Autonomous Community provides financial incentives (through inclusion in management, professional career or other type of financial incentive agreements considered by the Regional Health Service) to the services related to PROA activities that meet the objectives set by the hospital's PROA team.

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BM9. Estimation of human resources needed for implementing the PROA.

Clarifications

The calculation of the weekly hours is the result of adding up the dedication of all the members of the PROA team according to the needs identified in the centre's programme.

Benchmark level

Basic mandatory

A needs analysis is carried out, and the weekly dedication time of each person in the team who is assigned to the programme is calculated. \blacktriangle O

Evidence

A request will be issued for a report with the human resources needs analysis, specifying the weekly time that would be necessary for each member of the PROA team and the people involved in it.

Advanced mandatory

Availability of professionals with specific part-time availability (one Full Time Equivalent (35 h/week) per 500 beds) distributed among different specialities for PROA activities.

Evidence

In addition to the evidence of the basic mandatory level, a request will be issued for the document accrediting the availability of part-time professionals (35 h/week per 500 beds) for PROA activities during the working day.

Excellent mandatory

Availability of professionals with exclusive full-time availability (one Full Time Equivalent (35 h/week) per 250 beds) distributed among different specialities for PROA activities.

Evidence

In addition to the evidence of the basic mandatory level, a request will be issued for the document accrediting the availability of full-time professionals (35 h/week per 250 beds) for PROA activities during the working day will be requested.

BM10. Availability of technical resources.

Clarifications

This indicator is graded according to the technical resources available to the organisation.

- Benchmark level Basic mandatory
 - Pharmacy: having sufficient IT resources to calculate the Defined Daily Dose (DDD) in a standardised way (see benchmark 11).
 - benchmark 12).

Evidence

Confirmation that the hospital has a software application for automatic DDD calculation and that it has the technical resources to perform cumulative antibiotic sensitivity reporting.

Basic non-mandatory

 Pharmacy: having the IT resources to calculate days of therapy (DOT) in a standardised way for those services where DDD calculation is not valid.

Evidence

Confirmation that the hospital has a software application for automatic calculation of DOTs.

Advanced mandatory

- (ICU)) and IT alerts.
- including specific resistance mechanism characterisation.

Evidence

Confirmation that the hospital has electronic prescription and IT alerts and that it has the technical resources to conduct specific resistance mechanism studies.

Microbiology: having the means to perform cumulative antibiotic sensitivity reporting (see

• Pharmacy: having electronic prescriptions (>80% hospital beds and intensive care units

Microbiology: having the means to perform cumulative reporting of antibiotic sensitivity





Excellent mandatory

- Pharmacy: having electronic prescriptions assisted by dosing advice and also incorporating each centre's updated antimicrobial therapy guide (or the guide that may have been adopted by the centre) as a decision-making support tool. This tool will also report on antibiotics subject to safety alerts or antibiotic prescriptions in special populations, and identify patients with contraindications or special precautions for antibiotic use: patients with kidney or liver failure, or other special situations that might require a dose adjustment. In these cases, the steps to be taken in each case (switching to an alternative, adjusting the dose, etc.) should be indicated.
- **Microbiology:** having the necessary means to carry out molecular epidemiology studies.

Evidence

Confirmation that the hospital has an electronic prescription tool with the features defined in the benchmark and that it has the technical resources to carry out molecular epidemiology studies.

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BM11. The PROA team defines measurable indicators (both process and outcome) to assess the degree of achievement of the objectives set out in the **PROA Framework Document.**

Clarifications

The minimum indicators to be measured according to the benchmark level are included, as well as who is responsible for measuring them.

Benchmark level

Basic mandatory

Antimicrobial Use Indicators (pharmacy)

Annual measurement of the total consumption of antimicrobials in defined daily doses (DDD) per 1000 stays following the ATC classification. The report must specify 100% of the hospital's prescriptions. Consumption of all services that do not generate stays is excluded..

Sensitivity indicators (microbiology) Annual cumulative antibiotic sensitivity reports should be performed (see benchmark 12).

Basic non-mandatory

Antimicrobial Use Indicators (pharmacy)

For services where the calculation of the DDD indicator is not applicable, an annual calculation of Days of Therapy (DOT) per 1000 stays is recommended. Example: paediatrics, nephrology...

Advanced mandatory

Antimicrobial Use Indicators (pharmacv)

Measuring antimicrobial consumption annually according to ATC classification and stratifying by service or unit (ICU, grouped medical services and grouped surgical services).

Resistance indicators (microbiology)

Annual register of multidrug-resistant microorganisms in the centre including extended spectrum beta-lactamase-producing (ESBL-producing) and/or carbapenemase-producing enterobacteriaceae, multidrug-resistant Pseudomonas aeruginosa, multidrug-resistant Acinetobacter baumannii, methicillin-resistant Staphylococcus aureus and Clostridioides difficile, and calculate: (a) the percentages of each of them in relation to the total number of susceptible strains; (b) their incidence density (number of isolates in clinical samples per patient/1000 stays).

Clinical indicators (clinical)

Annually measuring crude mortality (%) of patients with the five leading causes of bacteraemia in the centre at 14 days excluding coagulase-negative staphylococci

Excellent mandatory

Antimicrobial Use Indicators (pharmacy)

- Measure guarterly antibiotic consumption in DDD and DOT per 1000 stays and per 1000 admissions following the ATC classification and stratifying by service or unit (ICU, grouped medical services, grouped surgical services and paediatric services). - Including the evolution of consumption of all families of antibiotics by ATC classification.

Resistance indicators (microbiology)

- Quarterly register of multidrug-resistant microorganisms in the centre including extended spectrum beta-lactamase-producing (ESBL-producing) and/or carbapenemase-producing enterobacteriaceae, multidrug-resistant Pseudomonas aeruginosa, multidrug-resistant Acinetobacter baumannii, methicillin-resistant Staphylococcus aureus and Clostridioides difficile, and calculate: (a) the percentages of each of them in relation to the total number of susceptible strains; and (b) their incidence density (number of isolates in clinical samples per patient/1000 stays).

- Breakdown by hospital units/services (ICU, grouped medical services, paediatric services and grouped surgical services).

Clinical indicators (clinical)

- Quarterly measurement of 14-day crude mortality (%) of patients with the five leading causes of bacteraemia in the centre (excluding coagulase-negative Staphylococcus) stratifying the analysis by aetiology, by site of acquisition (nosocomial vs. other) and by degree of resistance (MRB vs. B non-MR).

- Conducting regular quality assessments of surgical antibiotic prophylaxis using process (ECDC).

guality indicators established by the European Centre for Disease Prevention and Control





Excellent non-mandatory

Clinical indicators (clinical)

- To evaluate the healthcare quality for patients with MRB bacteraemia on a quarterly basis, determining the following indicators: a) percentage of these bacteraemias caused by MRB attended by the PROA team expert; b) time from microbiological diagnosis to therapeutic recommendation by the PROA team expert; c) percentage of adequate empirical treatments of bacteraemias due to E. coli and S. aureus; d) crude mortality at 14 days and e) hospital stay to discharge.

Process indicators related to treatment duration

- Annual measurement of the percentage of number of treatments lasting longer than 7 days/number of total antibiotic treatments. Stratifying by service.

> No. of treatments lasting longer than 7 days X 100 No. of total antibiotic treatments

- Annual measurement of the number of patients with antibiotic therapy lasting more than 7 days/total number of patients admitted during one year x 1000. Stratifying by service.

X 1000

No. of patients with a duration of more than 7 days

No. of patients admitted during one year

Evidence

Record with the data of the indicators set by the benchmark level and by monitoring them. The results of the indicators and the person responsible for their measurement shall be consigned in the annual monitoring report.

BM12. Annual cumulative sensitivity data.

Clarifications

One isolate per patient must be included. The breakpoints recommended by the latest published version of the European Committee on Antimicrobial Susceptibility Testing (EUCAST) are used. The selection of microorganisms and resistance mechanisms, and antibiotics for these reports are made in agreement with the infections control team or the Infections and Antibiotics Commission.

Benchmark level

Basic mandatory

out-of-hospital and in-hospital (ICU and postoperative resuscitation samples are classified individually).

Evidence

A request will be issued for the cumulative antimicrobial resistance report.

Advanced mandatory

Cumulative antibiotic sensitivity reports are performed semi-annually per service or per unit. Additionally, specific resistance mechanism characterisation reports need to be prepared.

Evidence

A request will be issued for the cumulative antimicrobial resistance report and annual reports on specific resistance mechanism characterisation.

Excellent mandatory

Cumulative antibiotic sensitivity reports are performed quarterly by service or by unit, in addition to annual molecular epidemiology reports for the centre. \blacktriangle

Evidence

A request will be issued for the cumulative antimicrobial resistance report and annual molecular epidemiology reports for the centre.

Annual cumulative antibiotic sensitivity reports are produced, disaggregating samples into



BM13. Development of selective report based on type of sample, microorganism and resistance profile.

Clarifications

The list of antibiotics included in the antibiogram is adapted to the type of sample and the microorganism causing the infection.

Benchmark level
 Excellent non-mandatory

Evidence

A request will be issued for evidence of the availability of a sensitivity report or antibiogram adapted to the type of sample and microorganism causing the infection.

BM14. The interpretation of phenotypes associated with resistance mechanisms shall be included in the cumulative antibiotic sensitivity reports.

- Clarifications
- N/A
- Benchmark level Advanced non-mandatory

Evidence

Resistance reports will be examined for evidence that the interpretation of phenotypes associated with resistance mechanisms has been included.

BM15. Cumulative reporting of antibiotic sensitivity shall also be done on the basis of epidemiological cut-off points (ECOFF).

- Clarifications N/A
- Benchmark level Excellent non-mandatory

Evidence

Resistance reports will be examined for evidence that the epidemiological cut-off points (ECOFF) have been taken into account.

BM16. The analysis of indicator results is presented to the Infections and Antibiotics Commission and, through general meetings, to the other members of the hospital.

Clarifications

The dissemination of these results is accompanied by information on the clinical justification for adjusting antimicrobial prescribing, highlighting the relevance of safety and healthcare quality aspects.

Benchmark level Basic mandatory

There is a yearly dissemination of the analysis of the results of the PROA process indicators, antimicrobial consumption and bacterial sensitivity data to the Infections and Antibiotics Commission and to all hospital departments. The annual presentation of the analysis of indicator results is made during a general meeting to the hospital services.

Evidence

A request will be issued for records substantiating that reports have been sent and submitted to the Infections and Antibiotics Commission and to all hospital services, as well as records of general meetings.





Advanced mandatory

Annual presentation of the analysis of indicator results to each of the hospital's main care services/units during clinical sessions. \blacktriangle

Evidence

A request will be issued for records substantiating that reports have been sent and presented to the Infections and Antibiotics Commission and to all hospital departments, as well as records substantiating that the presentation of the analysis of indicator results in clinical sessions has been done annually.

Excellent non-mandatory

Semi-annual presentation of the analysis of indicator results to each of the main care services/units during their clinical sessions. \blacktriangle

Evidence

A request will be issued for records substantiating that reports have been sent and submitted to the Infections and Antibiotics Commission and to all hospital services, as well as records substantiating that analysis of indicator results in clinical sessions have been submitted on a six-monthly basis.

BM17. Quality assessment of antimicrobial prescribing are conducted.

Clarifications

These assessments of the quality of prescribing are carried out to determine whether the actions taken (including training of professionals, ongoing clinical advisories, information campaigns, etc.) are effective, and to detect areas for improvement. Assessments are carried out through cross-sectional studies or through ongoing advisories. The advisories have two objectives: educational and evaluative. It is an activity on a real clinical case, non-impositional and carried out by peers, which allows to review the basics of the use of antibiotics with the prescribing physician and also to evaluate the quality of the prescription.

• Common indicator to be measured: percentage of adequate antimicrobial treatments out of the total number of treatments evaluated, overall and stratified according to indication: perioperative prophylaxis, empirical and targeted.

Advanced non-mandatory

Cross-sectional studies to assess whether the prescription has been appropriate according to hospital guides on an annual basis. \blacktriangle

Evidence

A request will be issued for the cross-sectional study on the adequacy of antibiotic prescriptions.

Excellent non-mandatory

Ongoing clinical advisories to assess whether th annual basis. $\blacktriangle \land \checkmark \checkmark \checkmark$

Evidence

In addition to the advisories, annual cross-sectional studies will be requested to assess the appropriateness of the prescription.

Ongoing clinical advisories to assess whether the prescription has been appropriate on an





BM18. An annual analysis is carried out on the level of compliance with objectives according to PROA indicators, with improvement plans and the setting of new objectives according to these. \blacktriangle •

- Clarifications N/A
- Benchmark level Basic mandatory

Evidence

The monitoring of objectives, indicators and improvement plans will be analysed. The documentation shall be included in the monitoring report.

BM19. Benchmark 11 results are published on the centre's website.

- Clarifications
- N/A
- Benchmark level Basic mandatory

Evidence

Confirmation that the results of benchmark 11 indicators are available on the Intranet.

BM20. An annual monitoring report is prepared that has to be accredited with the signature of the centre's medical board. \blacktriangle \bigcirc

Clarifications

The annual monitoring report, carried out by the PROA team, encompasses the outcome of various benchmarks developed in the Hospital PROA Team Certification Standard so that centre management is satisfied with the updates and has an overview of the outcome of the PROA activities in their hospital. At the discretion of the PROA team, it can be disseminated in full or in part to the Infections and Antibiotics Commission and to hospital departments. The documentation to be included is:

- The minutes of the PROA team meetings described in benchmark 5.
- The set of reports collected in benchmark 11.
- The analysis of the results of the PROA process indicators, antimicrobial consumption, and bacterial sensitivity data, defined in benchmark 16.
- The report on the level of compliance with the PROA objectives and improvement plans, described in benchmark 18.
- The records of the advisories carried out at the centre, provided they are carried out as defined in benchmark 23.
- Any modification of the PROA Framework Document.
- Benchmark level Basic mandatory

Evidence

A request will be issued for annual monitoring reports to substantiate that the points detailed in the benchmark are included. Confirmation that it has been signed by the medical board of the centre.





BM21. Development of an ongoing training programme on the use of antimicrobials for hospital units and services involved in the prevention, diagnosis and treatment of infections.

- Clarifications
- Benchmark level Basic mandatory

Development of an annual comprehensive training programme to be presented to the main services involved in the prevention, diagnosis and treatment of patients with infectious diseases in the hospital. \blacktriangle

Evidence

A request will be issued for the plan of the comprehensive training programme and attendance records in order to certify that it has been carried out.

Advanced mandatory

Development of a training programme in antibiotic use adapted to the specific characteristics of the department/unit to be delivered to the departments identified by the PROA team as critical. At least one specific programme per year is recommended. \blacktriangle

Evidence

A request will be issued for the plan of the comprehensive and specific training programme, adapted to the service/unit identified as critical in the antibiotic use and the attendance records in order to certify that they have been carried out.

BM22. Inclusion of the training activities in the objectives of each service and its professionals.

- Clarifications
- Benchmark level Advanced non-mandatory

Evidence

It shall be accredited that the units of the centre include training activities within their individual objectives.

BM23. Carrying out clinical advisories and interconsultations by members of the PROA team.

Clarifications

Advising is a training activity, not impositional by peers. The basics of diagnosis and antimicrobial therapy are reviewed on a real case chosen at random with the prescribing physician.

Benchmark level Basic mandatory

Evidence

Analysis of the records of clinical advisories and interconsultations carried out by the PROA team in the last year. The number of advisories based on real clinical cases will be counted.



BM24. Include training on the centre's **PROA** programme for specialists-in-training.

Clarifications N/A

Benchmark level Basic mandatory

Inclusion of the PROA implemented in the hospital as part of complementary training of specialists-in-training by agreement with the Teaching Commission. \blacktriangle 0

Evidence

Confirmation that the training plan for specialists-in-training includes complementary training on the centre's PROA.

Advanced mandatory

Inclusion of the PROA implemented in the hospital in the specific and compulsory training plan for specialists-in-training by agreement with the Teaching Commission. $\triangle \triangle \bigcirc$

Evidence

Confirmation that the training plan for specialists-in-training includes specific and compulsory training on the centre's PROA.

Excellent non-mandatory

Availability of specific rotation of residents with the PROA team.

Evidence

The centre's educational pathways will be presented.

BM25. Use of e-learning tools.

- Clarifications N/A
- Benchmark level
 Excellent non-mandatory

Evidence

Confirmation that the centre has and uses e-learning tools.

BM26. Pharmacotherapy guide: there is a standardised procedure for inclusion/ exclusion of antimicrobials including the report of the PROA team.

Clarifications

For the inclusion of new antimicrobials, the Guide for the assessment of Inclusion of New Drugs (GINF) should be used, taking into account the therapeutic positioning reports of <u>REvalMed</u> (SNS Medicines Evaluation Network) related to antimicrobials.

Benchmark level Basic mandatory

Evidence

A request will be issued for the standardised procedure for inclusion/exclusion of antimicrobials and for confirmation that the inclusion of new antimicrobials is done following the <u>GINF</u> guidelines, taking into account the therapeutic positioning reports of <u>REvalMed</u> related with antimicrobials.





BM27. Capacity of the centre to carry out PROA activities 24 hours a day every

day of the year. 🔺 🛦 🖉

Clarifications

Physical availability is not necessary. Clinical/microbiological assistance can be provided by telephone.

Benchmark level Excellent non-mandatory

Evidence

A request will be issued for records of the activity carried out during the emergency to ascertain that the centre is capable of carrying out PROA activities 24/7.

HOSPITAL PROA TEAM CERTIFICATION STANDARD





BM28. Preparation and periodic updating of the local guide for diagnosing and treating the main infectious diseases guided by the epidemiology of the centre. **A** O

Clarifications

Revision of the guide should be carried out whenever annual microbiological data so recommend. A reference guide can be adopted that is valid for the local epidemiological situation.

Benchmark level

Basic mandatory

Evidence

A request will be issued for the centre guide including the record of the dated modifications.

BM29. The centre has a clinician with expertise in diagnosing and treating infectious diseases who is consulted through related interconsultations.

- Clarifications N/A
- Benchmark level Basic mandatory

Evidence

A request will be issued for curriculum vitae substantiating the clinical expertise in the diagnosis and treatment of infectious diseases.

BM30. Real-time computerised access to analytical, microbiological, radiological and therapeutic patient data must be available.

- Clarifications N/A
- Benchmark level Advanced mandatory

Evidence

microbiological, radiological and therapeutic patient data must be available.

Clarifications

administration guideline and dose, assessment of possible allergies, compatibility and timing of infusions, and drug stability.

Benchmark level Advanced non-mandatory

Protocols to ensure safe antimicrobial administration are in place.

Evidence

administration.

Excellent mandatory

Certifying that agreed protocols are in place and complied with.

Evidence

month, verifying that the procedure for safe administration of antimicrobial treatment has been adhered to in at least 90% of the cycles.





BM32. There are support programmes in place for managing patients with bacteraemias. **A A O**

Clarifications

The minimum prerequisites for accrediting the existence of the programme are: 1) the team of professionals who carry it out; 2) a standard operating procedure defining how they carry it out on a daily basis; and 3) a record of the programme's activity.

Benchmark level

Advanced mandatory

Evidence

A request will be issued for support programmes for managing patients with bacteraemia.

BM33. There are support programmes in place for managing patients with infections caused by difficult-to-treat microorganisms.

Clarifications

The minimum prerequisites for accrediting the existence of the programme are: 1) the team of professionals who carry it out; 2) a standard operating procedure defining how they carry it out on a daily basis; and 3) a record of the programme's activity.

Benchmark level Advanced mandatory

Evidence

A request will be issued for support programmes for managing patients with infections caused by difficult-to-treat microorganisms.

BM34. Warning systems for inadequate dosing are in place.

- Clarifications N/A
- Benchmark level Basic non-mandatory

Evidence

Proof shall be submitted of the existence of warning systems with this capability in place.

BM35. Qualified personnel are available to detect and modify inadequate dosing based on PK/PD strategies.

- Clarifications N/A
- Benchmark level

Advanced non-mandatory

Having a capability to determine plasma levels of vancomycin and aminoglycosides to allow dose adjustment based on PK/PD indicators.

Evidence

Evidence to be provided that the centre has the capacity to determine plasma levels of vancomycin and aminoglycosides that allow dose adjustment based on PK/PD indicators, providing the number of out-of-range treatments that, after dose correction based on PK/PD indices, were brought to the reference values over a year.

49





Excellent mandatory

Determining plasma levels of antimicrobials that allow dose adjustment based on PK/PD indicators, taking as reference concentrations from population models and their relationship with minimum inhibitory concentration (MIC) values. In addition, the centre should have software applications for interpreting antimicrobial concentrations and providing subsequent recommendations of dose adjustments.

Evidence

Evidence to be provided that the centre has the capacity to determine plasma levels of antimicrobials that allow dose adjustment based on PK/PD indicators, taking as reference concentrations from population models and their relationship with minimum inhibitory concentration (MIC) values, providing the number of treatments that were adjusted over a year to PK/PD indicators. In addition, evidence should be provided as to whether the centre has software applications for interpreting antimicrobial concentrations and providing subsequent recommendations of dose adjustments.

BM36. There are warning systems in place for disparity between bacterial sensitivity and prescribed antibiotic.

- Clarifications
- N/A
- Benchmark level Excellent non-mandatory

Evidence

Evidence to be provided that warning systems are in place for disparity between bacterial sensitivity and the prescribed antibiotic.

BM37. Rapid tests are used to identify resistant microorganisms that allow early optimisation of treatments.

- Clarifications
- Benchmark level Advanced non-mandatory

Evidence

A request will be issued for a list of rapid tests used for identification of resistant microorganisms from the PROA team.

BM38. Audits are carried out to evaluate the quality of prescribing.

Clarifications

Audits are based on an evaluation of a prescription and the creation of specific recommendations for prescribers, without these recommendations implying restrictive or impositional action on the prescription. Audits should be carried out in real time. The PROA team designs an audit programme and decides who to target based on historical consumption and resistance data. Units with the highest number of prescriptions should have pre-set objectives. The audits focus on prescription evaluation and are non-impositional and conducted in real time.

Benchmark level Advanced non-mandatory

Evidence

A request will be issued for the audit programme specifying pre-set objectives and the audit log.





BM39. The hospital has a computerised decision support system for the PROA teams based on the integration of pharmacological, microbiological, epidemiological and clinical data. $\triangle \triangle \triangle$

- Clarifications
 N/A
- Benchmark level Excellent non-mandatory

Evidence

Evidence to be provided that the centre has a computerised decision support system for the PROA teams.

BM40. Protocols for Home Intravenous Antimicrobial Therapy (HIVAT) are available for treatment of outpatients with hospital antibiotics.

Clarifications N/A

Benchmark level Excellent mandatory

Evidence

A request will be issued for information on programmes implemented in coordination with primary healthcare, for treatment of outpatients with hospital antibiotics.



HOSPITAL PROA TEAM CERTIFICATION STANDARD

HOSPITAL PROA TEAM CERTIFICATION STANDARD



Typology VII. Measures to promote coordination between healthcare levels and continuity of healthcare

A. Standardisation of the activities of the PROA teams for community patients and hospital patients. In order to achieve the objectives indicated in the following benchmarks, there is a procedure for communicating and coordinating among the teams in different areas, with at least one meeting per year to discuss common goals. A A O

Clarifications

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For coordination between the two healthcare levels, it is recommended that at least one meeting be held annually. The coordinators of the community and hospital PROAs or, failing that, the members of the PROA team appointed by the coordinator, are responsible for this coordination. Participation of core team of community and hospital PROA teams is recommended. The meetings of the community and hospital PROA teams will be held with the following objectives:

- Evaluating the results of the previous year's objectives.
- Agreeing on objectives for the new year.
- Identifying areas for improvement.
- Deciding on intervention measures to be carried out.
- Reaching a consensus on the approach to the treatment of infections in outpatients, using the reference antimicrobial therapy guide for infections in the community as a basis.
- Developing coordination mechanisms to promote the achievement of common quality benchmarks for PROA certification.

Benchmark level

Advanced mandatory

Evidence

- A request will be issued to community and hospital PROA teams for the following:
- Minutes of the meetings held.
- Reports justifying shared actions.
- Objectives, showing that they have been followed up.
- Coordination or collaboration agreements.
- Agreed guide on antimicrobial therapy of community-acquired infections.

B. Annual local sensitivity data for the most frequent pathogens in the community are available for professionals working in primary healthcare and the hospital according to the PRAN indicators (updated in Annex II).

Clarifications

This indicator depends on the activity of the microbiology laboratory of the referral hospital(s) and the provision of cumulative bacterial sensitivity reports from samples from the community (primary healthcare, hospital emergency and, if possible, hospital outpatient clinics). One isolate per patient must be included. The cut-off points recommended by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) are used. The selection of microorganisms, resistance mechanisms and antibiotics for these reports should be in line with those established by the PRAN for Community PROAs, listed in Annex II. It is recommended that the data be disaggregated by age, sex and place of origin (specifying whether the data come from the Emergency Department of the referral hospital or from social-health centres).

Benchmark level Basic mandatory

to professionals working in primary healthcare and in the hospital.

Evidence

A request will be issued to community and hospital PROA teams for evidence of the availability of annual sensitivity data from the referral hospital's microbiology laboratory following the standards set out by EUCAST.

Advanced mandatory

Annual local sensitivity data, disaggregated by age, for the most prevalent pathogens in the community are available to professionals working in primary healthcare and in the hospital.

Evidence

A request will be issued to community and hospital PROA teams for evidence of the availability of annual sensitivity data (disaggregated by age) from the referral hospital's microbiology laboratory following the standards set out by EUCAST.

Annual local sensitivity data for the most frequent pathogens in the community are available



Excellent non-mandatory

Annual local sensitivity data, disaggregated by age, sex and place of origin, of the most frequent pathogens in the community, are available to professionals working in primary healthcare and in the hospital. $\triangle \triangle$

Evidence

A request will be issued to community and hospital PROA teams for evidence of the availability of annual local sensitivity data (disaggregated by age, sex and place of origin) from the referral hospital's microbiology laboratory following the standards set out by <u>EUCAST</u>.

C. An antibiogram template for primary healthcare is designed by agreement between the primary healthcare area and the reference laboratory, adapted to the type of samples from community infections.

Clarifications

The antibiogram issued to primary healthcare should be easily interpretable and report the clinical category – standard sensitive exposure (S), increased exposure (I) or resistant (R) – of the antibiotics included in the SNS antimicrobial therapy guides.

Benchmark level

Excellent non-mandatory

Evidence

A request will be issued to community and hospital PROA teams for evidence of the availability of the sensitivity report or antibiogram adapted to primary healthcare.

D. A representative microbiologist and a clinician with expertise in diagnosing and treating hospital-acquired infectious diseases (for adults and paediatrics) are assigned to advise the PROA team on the community patient in their referral area.

Clarifications

It is recommended that a representative microbiologist be appointed for the community PROA, as well as an expert in hospital infectious diseases (adults and paediatrics). Both should preferably be members of the hospital PROA team. If the area has more than one referral hospital, a microbiologist and an infectious disease physician should be available for each one.

Benchmark level

Advanced mandatory

Evidence

A request will be issued for records of the availability of a microbiologist and an infectious disease expert for consultations and records of the activity.

E. Hospital referral protocols are available for the most prevalent infectious pathologies agreed with the referral hospital(s). $\blacktriangle \blacktriangle \checkmark$

Clarifications

These protocols or criteria may be incorporated in the reference antimicrobial guide and may be requested to accredit this benchmark.

Benchmark level

Advanced non-mandatory

Evidence

A request will be issued for protocols or criteria for referral to hospital services implemented in coordination with the referral hospital(s) for patients requiring shared management, or the agreed antimicrobial therapy guide for infections in the community where this information is included.



Typology VII. Measures to promote coordination between healthcare levels and continuity of healthcare

F. The health area has computerised access to the analytical, microbiological and radiological results of the patients attending the referral hospital.

Clarifications

This indicator depends on the activity of the referral hospital and should be available for primary healthcare.

Benchmark level

Advanced mandatory

Evidence

A request will be issued for records of the availability of a microbiologist and a disease expert. A request will be issued for community and hospital PROA teams to provide evidence that professionals working in primary healthcare have computerised access to patients' analytical, microbiological and radiological results in real time.

G. There is a procedure to check for suspected antibiotic allergy and recording it in the patient's medical record.

Clarifications

Any suspected allergy to antibiotics, especially beta-lactams, should be studied and confirmed or ruled out and the result should be correctly recorded in the patient's medical record. This procedure should include a specific referral circuit to the allergy service for examination in this unit when necessary. The results must be correctly recorded in the digital medical record and the alert included in the prescription.

Benchmark level

Excellent non-mandatory

Evidence

A request will be issued to community and hospital PROA teams for evidence of the availability of a procedure to check for suspected allergies by the allergology and/or immunology service.

H. Alert mechanisms are in place (coordinated between the referral hospital and the primary healthcare area) to identify patients discharged from hospital or patients in the community who are admitted to hospital with an infection or colonisation by multidrug-resistant microorganisms, to facilitate their follow-up and optimise recommended steps.

Clarifications

In the case of patients in the community, these are patients with known colonisation or infection with multidrug-resistant bacteria.

Benchmark level Excellent non-mandatory

Evidence

A request will be issued to community and hospital PROA teams to provide information on the programmes implemented in coordination between the referral hospital and the primary healthcare area, and which are activated when a transition of care of a patient with infection or colonisation by multidrug-resistant microorganisms is detected, with specific recommendations on approach (treatments, isolation measures, etc.).

I. Coordinated action protocols are in place for the detection, reporting and response to episodes of bacteraemia in outpatients. $\blacktriangle \blacktriangle \odot$

Clarifications

In particular, action will be envisaged for patients discharged from hospital emergency departments and followed up in primary healthcare.

Benchmark level

Advanced mandatory

Evidence

A request will be issued to community and hospital PROA teams for protocols for action and detection of bacteraemia in outpatients.





 Image: State of the second state of

J. Protocols are in place for detection, reporting and action in cases of identification of microorganisms of particular clinical and/or epidemiological relevance detected in samples (not blood cultures) from outpatients.

Clarifications

These cases would include multidrug-resistant bacteria and microorganisms without oral treatment options.

Benchmark level Advanced mandatory

Evidence

A request will be issued to community and hospital PROA teams for protocols for action in the event of identification of microorganisms of particular clinical and/or epidemiological relevance detected in samples (not blood cultures) from outpatients.





UNDERTAKING OF HOSPITAL MANAGEMENT WITH HOSPITAL PROA TEAM
with ID no,
medical director of the hospital in the
Autonomous Community of UNDERTAKES to promote the
activities foreseen in the PROA Framework Programme, to monitor and analyse the indicators,
and to disseminate the results of the PROA that has been set up in the hospital.
On 20
Signed: (name and surname)
Spanish Action Plan on Antibiotic Resistance

HOSPITAL PROA TEAM CERTIFICATION STANDARD





Map of antibiotic sensitivity in the community, target microorganisms and special-surveillance antibiotics

The scope of out-of-hospital cumulative reports is the health area or equivalent. Only samples of non-hospital origin are included and samples from hospital emergencies are excluded. For certain microorganisms of community origin such as Salmonella or Campylobacter, it could be considered to also include hospital samples. Samples for epidemiological surveillance are excluded.

Data are calculated using the first isolation of each patient and year.

If the total number of isolated microorganisms is less than 30, aggregation of data from several years can be considered.

Minimum frequency: annual.

Target microorganisms, sample type and % sensitivity to the following antibiotics (AB):

GRAM- microorganisms	Sample	AB1	AB2	AB3	AB4	AB5	AB6	AB7	AB8	AB9	AB10
Escherichia coli (E. coli)	Urine	AMP/ AMOX	A/C	СХМ	CTX/ CRO	CIP	FOS	FD	SXT	-	-
<i>E. coli</i> resistant to 3 rd generation cephalosporins/ESBL	Urine	-	A/C	-	CTX/ CRO	CIP	FOS	FD	SXT	-	-
Klebsiella pneumoniae	Urine	AMP/ AMOX	A/C	СХМ	CTX/ CRO	CIP	FOS	FD	SXT	-	-
<i>Klebsiella pneumoniae</i> resistant to 3 rd generation cephalosporins/ESBL	Urine	AMP/ AMOX	A/C	СХМ	CTX/ CRO	CIP	FOS	FD	SXT	-	-
Proteus mirabilis	Urine	AMP/ AMOX	A/C	СХМ	CTX/ CRO	CIP	FOS	-	SXT	-	-
Haemophilus influenzae	Respiratory tract	AMP/ AMOX	A/C	-	CTX/ CRO	CIP/ LEVO	-	-	-	-	-

GRAM+ microorganisms	Sample	AB1	AB2	AB3	AB4	AB5	AB6	AB7	AB8	AB9	AB10
Methicillin-sensitive Staphylococcus aureus (MSSA)	All	OXA/ CLOXA	ERI	CD	MUP	CIP/ LEVO	GM	тов	SXT	FUS	TET
Methicillin-resistant Staphylococcus aureus (MRSA)	All	OXA/ CLOXA	ERI	CD	MUP	CIP/ LEVO	GM	тов	SXT	FUS	TET
Streptococcus pyogenes	Pharyngeal exudate	-	ERI	CD	-	-	-	-	-	-	-
Streptococcus pneumoniae	Respiratory tract	PEN/AMOX	ERI	CD	CTX/ CRO	LEV	-	-	-	-	-

A/C: amoxicillin/clavulanate; AMP/AMOX: ampicillin/amoxicillin; ESBL: extended-spectrum beta-lactamases, (resistant to 3rd generation cephalosporins; not all 3rd generation cephalosporin resistances respond to ESBL production, although the vast majority does); CD: clindamycin; CXM: cefuroxime; CTX: cefotaxime; CRO: ceftriaxone (CTX and CRO are equivalent sensitivity effects); CIP: ciprofloxacin; ERI: erythromycin; FOS: fosfomycin; FUS: fusidic acid; FD: nitrofurantoin; GM: gentamicin; MUP: mupirocin; OXA: oxacillin (defines methicillin resistance); PEN: penicillin; SXT: trimethoprim-sulfame-thoxazole or co-trimoxazole; TET: tetracycline; TOB: tobramycin.

Other microorganisms to be considered in terms of overall incidence:

Target microorganisms, sample type and % sensitivity to the following antibiotics (AB):

Microorganisms	Sample	AB1	AB2	AB3	AB4	AB5
Salmonella spp.	Faeces	AMP/ AMOX	CTX/ CRO	CIP	SXT	-
Campylobacter spp.	Faeces	-	-	CIP	-	ERI

AMP/AMOX: ampicillin/amoxicillin; CTX: cefotaxime; CRO: ceftriaxone; CIP: ciprofloxacin; SXT: trimethoprimsulfamethoxazole; ERI: erythromycin (defines resistance to azithromycin).





Indicators of multidrug-resistant bacteria

Microorganisms	Sample	No. of isolates	No. of resistant isolates	% of resistant isolates
E. coli resistant to amoxicillin/clavulanate	Urine			
E. coli resistant to ciprofloxacin	Urine			
E. coli ESBL	Urine			
Klebsiella pneumoniae ESBL	Urine			
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	All			
Streptococcus pneumoniae resistant to penicillin	Respiratory tract			
Streptococcus pneumoniae resistant to 3 rd generation cephalosporins	Respiratory tract			
<i>Streptococcus pyogenes</i> resistant to erythromycin	Respiratory tract			
Haemophilus influenzae resistant to amoxicillin- clavulanate	Respiratory tract			
Salmonella spp. resistant to ciprofloxacin	Faeces			





Basic mandatory level $\blacktriangle {\ \bullet \ }$

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	1	Constitution of the PROA team.	Minutes of the Infections and Antibiotics Commission meeting in which the PROA team is constituted and approved.	Single document	0
	2	Appointment of core team.	Professional category of each member of the PROA team.	Single document	0
	3	Definition of functions.	List of functions of the members of the PROA team.	Latest update	\bigcirc
	4	Preparation of the PROA Fra- mework Document.	PROA Framework Document (includes the points detailed in the benchmark) signed by the medical director.	Single document	0
	5	Organisation and recording of PROA team activities.	Minutes of the meetings held and the follow-up of the decisions to the PROA team.	Previous year's record	\bigcirc
	6	Explicit support from the medical board and the Infections and Antibiotics Commission.	 Annex I. Minutes of the Infections and Antibiotics Commission. 	Single document	0
	9	Needs analysis, determining the necessary weekly dedi- cation time of each member of the PROA team.	Report with the human resources needs analysis, specifying the weekly time that would be necessary for each member of the PROA team and the people involved in it.	Latest update	0
	10	The pharmacy service has the IT resources to calculate DDD in a standardised way and the microbiology service has the means to produce cumulative antibiotic sensitivity reports.	Document substantiating that the hospital has a software application for automatic DDD calculation and the technical resources to perform cumula- tive antibiotic sensitivity reporting.	Latest update	0
IV	11	 Annual calculation: DDD/1000 stays according to <u>ATC</u> classification. Disaggregated (out-of-hospital and in-hospital) cumulative antimicrobial sensitivity report. 	Record with indicator data.	Annual	0
	12	Disaggregated reporting (out-of-hospital and in-hospi- tal) of cumulative antimicro- bial sensitivity.	Disaggregated reporting (out-of- hospital and in-hospital) of cumulative antimicrobial sensitivity.	Annual	0

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	16	 Analysis of the results of the indicators (process, consumption and sensitivity data): Dissemination to the Infections and Antibiotics Commission and to all hospital departments. Annual presentation at a general meeting to the hospital services. 	 Analysis of the outcome of the indicators: Records of delivery to the Infections and Antibiotics Commission and all hospital departments. Records of general meetings. 	Annual	0
	18	Evaluation of objectives and creation of improvement plans.	Analysis of the monitoring of the objectives, indicators and improvement plans.	Annual	0
	19	Publication of the results of the indicators on the centre's website.	Availability of the results of benchmark n° 11 indicators on the intranet.	Latest update	\bigcirc
	20	Preparation of the annual monitoring report.	Annual monitoring report (including the items detailed in the benchmark) signed by the medical board.	Annual	\bigcirc
	21	Comprehensive lifelong learning programme.	 Planning of comprehensive training programme. Attendance records. 	Annual	\bigcirc
	23	Clinical advisories and inter- consultations are carried out.	Records of clinical advisories sessions and interconsultations.	Annual	0
V	24	Further training of specia- lists-in-training by agreement with the Teaching Commis- sion.	Training plan for specialists-in-training includes complementary training on the centre's PROA.	Latest update	\bigcirc
	26	Standardised procedure for inclusion/exclusion of antimicrobials in the pharma- cotherapy guide.	Standardised procedure for the inclusion/exclusion of antimicrobials fo- llowing the <u>GINF</u> guidelines and taking into account the therapeutic positio- ning reports of <u>REvalMed</u> .	Latest update	\bigcirc
	28	Periodic updating of the lo- cal guide for diagnosing and treating the main infectious diseases guided by the epi- demiology of the centre.	Centre guide including record of modi- fications with dates.	Latest update	\bigcirc
	29	Availability of a clinician with expertise in diagnosing and treating infectious diseases for interconsultations.	Curriculum vitae evidencing clinical expertise in diagnosing and treating infectious diseases.	Latest update	\bigcirc

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HOSPITAL PROA TEAM CERTIFICATION STANDARD



ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
VII	В	Following the indicators in Annex II, annual local sensitivity data for the most frequent pathogens in the community.	Availability of annual local sensitivity data for the most frequent pathogens in the community from the microbiolo- gy laboratory of the referral hospital.	Annual	\bigcirc





ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	10	The pharmacy service has the IT resources to calculate DOTs in a standardised way.	Document certifying that the pharmacy service has a software application for automatic calculation of DOTs.	Latest upda te	0
IV	11	Annual calculation: DOT/1000 stays according to <u>ATC</u> classification.	Record with indicator data.	Annual	0
VI	34	Warning systems for inade- quate dosing.	Existence of warning systems for ina- dequate dosing.	Latest update	\bigcirc

HOSPITAL PROA TEAM CERTIFICATION STANDARD





Advanced mandatory level 🔺 👁

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	7	Inclusion of the PROA's goals in strategic objectives.	Hospital's strategic objectives to substantiate that the PROA is included among them.	Latest upda te	0
	9	Professionals with specific part-time availability for PROA activities. 35 h/week per 500 beds distributed among diffe- rent specialities for PROA activities.	 Evidence of the basic mandatory level. Document accrediting the availability of part-time professio- nals (35 h/week per 500 beds) for PROA activities during the working day. 	Latest upda te	0
	10	The pharmacy service has electronic prescription and IT alerts and the microbiolo- gy service has the necessary means to perform cumula- tive reporting of antibiotic sensitivity including specific resistance mechanism cha- racterisation.	Document that the hospital has electronic prescription and IT alerts and technical resources for specific resistance mechanism characterisation.	Latest update	0
	11	 Annual calculation: DDD/1000 stays stratified by service or by unit. Multidrug-resistant microor- ganisms. Crude mortality. 	Record with indicator data.	Annual	\bigcirc
IV	12	 Disaggregated (service) cumulative antimicrobial sensitivity report. Specific resistance me- chanism characterisation reports. 	 Disaggregated (service) cumulative antimicrobial sensitivity report. Specific resistance mechanism characterisation reports. 	 Semi-annually: disaggregated report on cumu- lative antimicro- bial resistance. Annually: spe- cific resistance mechanism characterisation reports. 	0
	16	 Analysis of the results of the indicators (process, consumption and sensitivity data): Dissemination to the Infec- tions and Antibiotics Com- mission and to all hospital departments. Annual presentation at the clinical sessions of each of the hospital's main care services/units. 	 Analysis of the outcome of the indicators: Records of delivery to the Infections and Antibiotics Commission and all hospital departments. Records of the clinical sessions of each of the hospital's main care services/units. 	Annual	0

TYP.	Benchmark	Summary	
V	21	Training programme in antibiotic use adapted to the specific characteristics of the department/unit.	 Planning program Planning adapted service/ Attenda mes.
	24	Specific and compulsory training of specialists-in- training by agreement with the Teaching Commission.	Training p includes ning on t
	30	Real-time computerised access to analytical, micro- biological, radiological and therapeutic patient data.	Ascertair real-time analytica and thera available
VI	32	Support programmes for managing patients with bacteraemia.	Support p patients v
	33	Support programmes for managing patients with infections caused by diffi- cult-to-treat microorganisms.	Support p patients v difficult-te

Evidence	Version to submit	Check- list	
g of comprehensive training nme. g of the training programme I to the characteristics of the unit. nce records for both program-	Annual	0	And and a series of the series
plan for specialists-in-training specific and compulsory trai- ne centre's PROA.	Latest update	\bigcirc	
ing that the PROA team has computerised access to , microbiological, radiological peutic patient data must be	Latest upda te	\bigcirc	Son and a series of the series
programme for managing vith bacteraemia.	Latest update	0	
programme for managing vith infections caused by p-treat microorganisms.	Latest update	0	

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TYP.	Benchmark	Summary	Evidence	Version to submit	Check- list
	Α	Mechanism of communi- cation and coordination between the PROA teams of the hospital patient and the community patient, with at least one annual meeting to discuss common objectives.	 Minutes of the meetings held. Reports justifying shared actions. Objectives, showing that they have been followed up. Coordination or collaboration agreements. The agreed guide on antimicrobial therapy of community-acquired infections. 	Annual	0
	В	Following the indicators in Annex II, annual local sensi- tivity (disaggregated by age) data for the most frequent pathogens in the community.	Availability of annual local sensitivity data (disaggregated by age) of the most frequent pathogens in the com- munity from the microbiology labora- tory of the referral hospital.	Annual	0
VII	D	Appointment of a microbio- logist and a clinician with expertise in diagnosing and treating hospital-acquired in- fectious diseases (for adults and paediatrics) to advise the community PROA team in their area of reference.	Record of the availability of a microbio- logist and an infectious disease expert and records of the activity.	Latest update	0
	F	The health area has access to the analytical, microbiolo- gical and radiological results of patients attending the referral hospital.	Evidence that professionals working in primary healthcare have computerised access to real-time analytical, micro- biological and radiological results of patients.	Latest update	0
	I	Coordinated action pro- tocols for the detection, reporting and response to episodes of bacteraemia in outpatients.	Coordinated action protocols for the detection, reporting and response to episodes of bacteraemia in outpatients.	Latest update	0
	J	Protocols for detecting, reporting and acting upon cases of identification of microorganisms of special clinical and/or epidemio- logical relevance found in samples (not blood cultures) from outpatients.	Protocols for detecting, reporting and acting upon cases of identification of microorganisms of special clinical and/ or epidemiological importance.	Latest upda te	0

HOSPITAL PROA TEAM CERTIFICATION STANDARD





Advanced non-mandatory level 🛦 🖉

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
IV	14	The interpretation of pheno- types associated with resis- tance mechanisms shall be included in the cumulative antibiotic sensitivity reports.	Sensitivity reports with interpre- tation of phenotypes associated with resistance mechanisms.	As per <u>benchmark</u> 12	0
	17	Annual evaluation of the quality of antimicrobial pres- cribing through cross-sectio- nal studies.	Report on the cross-sectional study on the adequacy of antibio- tic prescriptions.	Annual	0
V	22	Inclusion of the training activities in the objectives of each service and its profes- sionals.	Accreditation that the units of the centre include training activities within their individual objectives.	Latest update	0
	31	Protocols are in place to ensure safe antimicrobial administration.	Centre procedures/protocols for safe antimicrobial administration.	Latest update	0
VI	35	Determining plasma levels of vancomycin and amino- glycosides to allow dose adjustment based on PK/PD indicators.	Providing no. of treatments (van- comycin/aminoglocoside) out of range which, after a dose correction based on PK/PD indices, attained reference values over a one-year period.	Latest update	0
	37	Rapid tests for identification of resistant microorganisms.	List of rapid tests used for the identification of resistant microor-ganisms.	Latest upda te	\bigcirc
	38	Audits to evaluate the quali- ty of prescribing.	 Audit programme specifying pre-established objectives. Audit log. 	Latest update	0
VII	E	Hospital referral protocols for the most prevalent infec- tious pathologies.	Protocols or criteria for referral to hospital services for patients requiring shared management, or agreed antimicrobial therapy guide for infections in the community where this information is included.	Latest update	\bigcirc

HOSPITAL PROA TEAM CERTIFICATION STANDARD

HOSPITAL PROA TEAM CERTIFICATION STANDARD





Excellent mandatory level 🔺 🔺 💿

TYP.	Benchmark	Summary	Evidence	Version to submit	Check- list
	8	PROA objectives are linked to incentives.	Documentation certifying that the Autonomous Community provides financial incentives (through inclu- sion in management, professional career or other type of financial incentive agreements considered by the Regional Health Service) to the services related to PROA activities that meet the objectives set by the hospital's PROA team.	Latest update	0
	9	Professionals with exclusive full-time availability for PROA activities. 35 h/week per 250 beds distributed among di- fferent specialities for PROA activities.	 Evidence of the basic mandatory level. Document accrediting the availability of full-time professio- nals (35 h/week per 250 beds) for PROA activities during the working day. 	Latest update	0
	10	The pharmacy service has electronic prescriptions assisted by dosing advice and the microbiology service has the means to carry out molecular epidemiology studies.	Document certifying that the hospital has dosing advice-as- sisted prescribing and technical resources to carry out molecular epidemiology studies.	Latest update	0
IV	11	 Quarterly calculation: DDD, DOT/1000 stays, 1000 admissions. Including the evolution of con- sumption of all families of antibiotics by <u>ATC</u> classifi- cation. Multidrug-resistant microor- ganisms, disaggregated (hospital units/services). Crude mortality. Regular quality assessments of sur- gical antibiotic prophylaxis are conducted using process quality indicators established by the ECDC. 	Record with indicator data.	 Consumption, microbiological and clinical indicators on a quarterly basis. Periodic quality assessments of surgical antibio- tic prophylaxis. 	0
	12	 Disaggregated (service) cumulative antimicrobial sensitivity report. Molecular epidemiology reports from the centre. 	 Disaggregated (service) cumulative antimicrobial sensitivity report. Molecular epidemiology reports from the centre. 	 Quarterly disag- gregated cumu- lative antimicro- bial sensitivity report. Annually, mole- cular epidemio- logy reports from the centre. 	0

TYP.	Benchmark	Summary	Evidence	Version to submit	Check- list
	31	Compliance with protocols to ensure safe antimicrobial administration is certified.	Report of randomised review of 50 cycles of antimicrobial therapy indicated in the last month.	Latest update	0
VI	35	Determining plasma levels of antimicrobials taking as re- ference concentrations from population models and their relationship with minimum inhibitory concentration (MIC) values.	 No. of treatments that were adjusted over one year to the PK/PD indica- tors. The centre has software applications for interpreting antimicrobial concen- trations and providing subsequent re- commendations of dose adjustments. 	Latest update	0
	40	HIVAT protocols for treat- ment of outpatients with hospital antibiotics.	Information on HIVAT protocols for treatment of outpatients with hospital antibiotics, implemented in coordina- tion with primary healthcare.	Latest update	0





Excellent non-mandatory level 🔺 🛦 🖉

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	11	Quarterly evaluation: • Quality of care for patients with multidrug-resistant bacteraemia. Annually: • Process indicators rela- ted to treatment duration (percentage of the number of treatments lasting more than 7 days and of the number of patients with antibiotic therapy lasting more than 7 days).	Record with indicator data.	 Quarterly, health- care quality for patients with bacteraemia due to multidrug- resistant bacteraemia. Annually, pro- cess indicators related to treat- ment duration 	0
	13	Selective report based on sample type, microorganism and resistance profile.	Sensitivity report or antibiogram adapted to the type of sample and the microorganism causing the infection.	As per <u>benchmark</u> 12	0
IV	15	Cumulative reporting of anti- biotic sensitivity shall also be done on the basis of epide- miological cut-off points.	Sensitivity reports based on <u>ECOFF</u> .	As per <u>benchmark</u> 12	0
	16	Analysis of the results of the indicators (process, consumption and sensitivity data): • Dissemination to the Infections and Antibiotics Commission and to all hospital departments. • Semi-annual presentation at the clinical sessions of each of the hospital's main care services/units.	 Analysis of the outcome of the indicators: Record of delivery to the Infections and Antibiotics Commission and all hospital departments. Records of the clinical sessions of each of the hospital's main care services/units. 	Semi-annually	0
	17	Annual evaluation of the quality of antimicrobial prescribing through ongoing clinical advisories.	 Advisories carried out. Report on cross-sectional studies. 	Annual	0
	24	Availability of specific ro- tation of residents with the PROA team.	Centre's educational pathways.	Latest update	0
V	25	E-learning tools are availa- ble.	Availability and use of e-learning tools at the centre is confirmed.	Latest update	0
	27	Ability to carry out PROA activities 24/7.	Records of the activity carried out during the emergency.	Latest update	0

ТҮР.	Benchmark	Summary	Evidence	Version to submit	Check- list
	36	Warning systems for dis- parity between bacterial sensitivity and prescribed antibiotic.	Existence of warning systems for dis- parity between bacterial sensitivity and prescribed antibiotic.	Latest update	0
VI	39	Computerised decision support system for the PROA teams based on the inte- gration of pharmacological, microbiological, epidemiolo- gical and clinical data.	Evidence on the computerised decisio support system for PROA teams used.	n Latest update	0
	в	Following the indicators in Annex II, annual local sensi- tivity (disaggregated by age, sex and place of origin) data for the most frequent patho- gens in the community.	Availability of annual local sensitivity data (disaggregated by age, sex and place of origin) of the most frequent pathogens in the community from the microbiology laboratory of the referral hospital.	Annual	0
	С	Antibiogram template for pri- mary healthcare adapted to the type of infection samples from the community.	Sensitivity report or antibiogram adap- ted to primary healthcare.	Latest update	\bigcirc
VII	G	Procedure to check for sus- pected antibiotic allergy and recording it in the patient's medical history.	Availability of a procedure to check for suspected allergies by the allergology and/or immunology service.	Latest update	\bigcirc
	н	An alert mechanism to identify patients discharged from hospital or patients in the community who are admitted to hospital with infection or colonisation by multidrug-resistant microor- ganisms.	Programmes for patients with infection or colonisation by multidrug-resistant microorganisms with specific recom- mendations for their management (treatments, isolation measures, etc.).	Latest update	\bigcirc

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