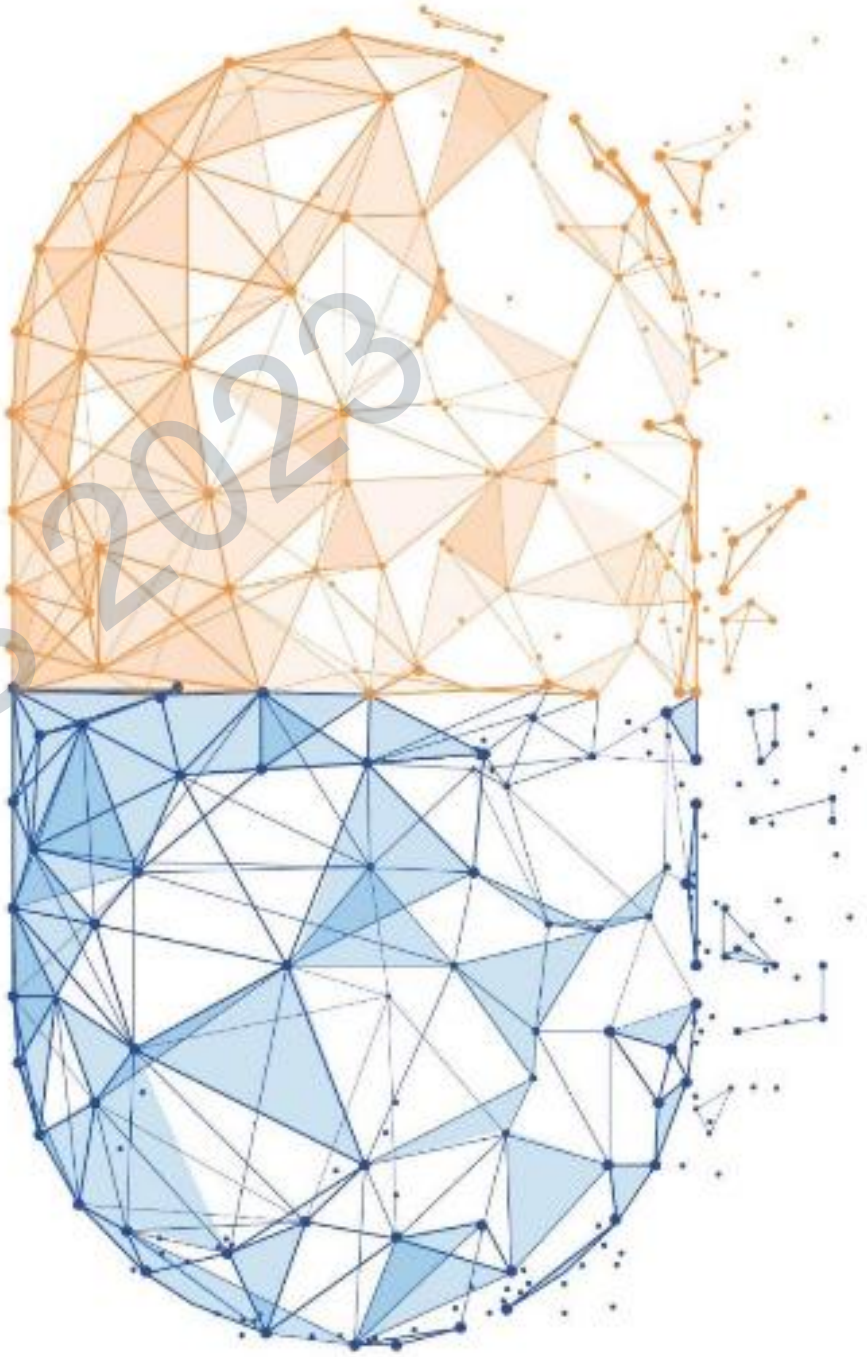
Farmacia: indicadores de uso adecuado de AB, cómo detectar puntos de mejora en la prescripción, gestión de desabastecimientos

Aurora Fernàndez Polo

Servicio de Farmacia Hospital Vall d'Hebron



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Vall d'Hebron
Barcelona Hospital Campus

15:30 Mesa Redonda 3: De la Política Antibiótica al PROA

Modera: Pilar Retamar Gentil, HUV Macarena

15:30 Microbiología: mapa de resistencias, vigilancia brotes.

Dra. Patricia Ruiz-Garbajosa, H Ramón y Cajal.

15:45 Farmacia: indicadores de uso adecuado de AB, cómo detectar puntos de mejora en la prescripción, gestión de desabastecimientos

Dra. Aurora Fernández, HU Vall D'Hebron,

16:00 Infecciosas: comunicación interna y externa. Guías terapéuticas, asesorías, programa bacteriemia.

Dr. Jose Molina Ruiz-Bermejo, HUV Virgen del Rocío..

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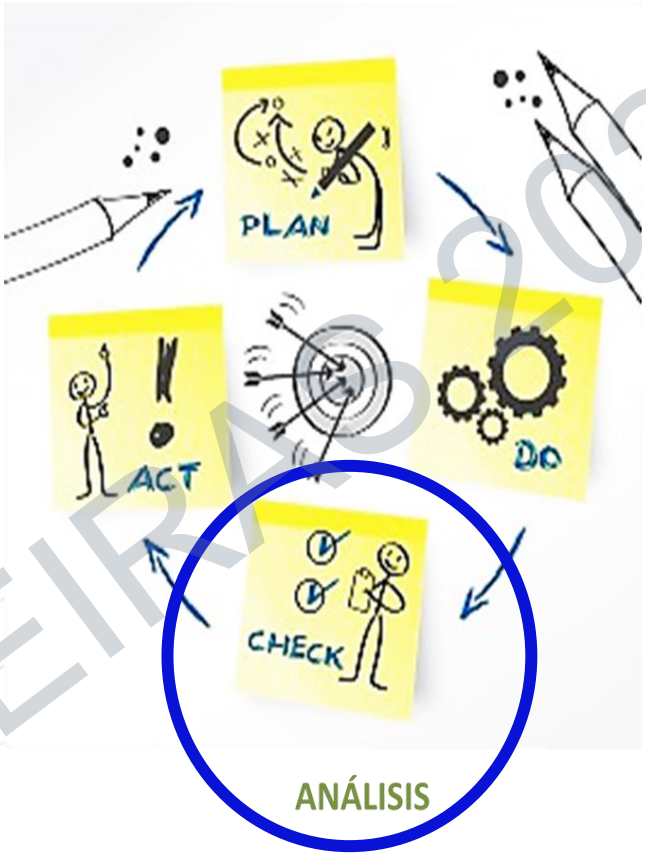
PROA

PLANIFICACIÓN



ACCIONES DE MEJORA

INICIATIVAS PROA
Auditorías
Monitorización
Formación

ANÁLISIS

"The right antibiotic for the right patient, at the right time, with the right dose, and the right route, causing the least harm to the patient and future patients"

www/cdc.gov/getsmart/healthcare/inpatient-stewardship

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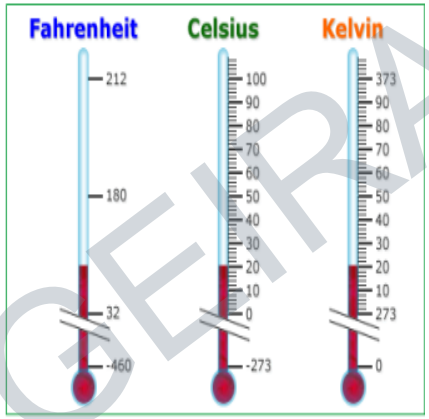
"If you cannot measure it, you cannot improve it"

Lord Kelvin 1824-1907



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Indicadores de uso adecuado de AB ¿Qué debemos medir?

IRAS 2023

Principales guías y recomendaciones

Enferm Infecc Microbiol Clin. 2012;30(1):22.e1–22.e23

Enfermedades Infecciosas y Microbiología Clínica
www.elsevier.es/eimc

Documento de consenso

Programas de optimización de uso de antimicrobianos (PROA) en hospitales españoles: documento de consenso GEIH-SEIMC, SEFH y SEMPSPH☆,☆☆

Jesús Rodríguez-Baño[a,*], José Ramón Paño-Pardo[b,*], Luis Alvarez-Rocha[c], Ángel Asensio[d], Esther Calbo[e], Emilia Cercenado[f], José Miguel Cisneros[g], Javier Cobo[h], Olga Delgado[i], José Garnacho-Montero[j], Santiago Grau[k], Juan Pablo Horcajada[l], Ana Hornero[m], Javier Murillas-Angoiti[n], Antonio Oliver[o], Belén Padilla[f], Juan Pasquau[p], Miquel Pujol[m], Patricia Ruiz-Garbajosa[q], Rafael San Juan[r] y Rafael Sierra[s]

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[b] Unidad de Enfermedades Infecciosas y Microbiología Clínica, Hospital Universitario La Paz-IDIPAZ, Madrid, España
[c] Servicio de Medicina Intensiva, Complexo Hospitalario Universitario de A Coruña, A Coruña, España
[d] Servicio de Medicina Preventiva, Hospital Puerta de Hierro, Madrid, España

ECDC DRAFT TECHNICAL REPORT

Proposals for draft EU guidelines on the prudent use of antimicrobials in human medicine

NICE National Institute for Health and Care Excellence

NICE quality standard

Antimicrobial stewardship

Quality standard
Published: 22 April 2016
nice.org.uk/guidance/qs121

Indicator Specification
Antimicrobial Stewardship
Clinical Care Standard
December 2015

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Clinical Care Standards

Clinical Infectious Diseases Advance Access published April 15, 2016

Clinical Infectious Diseases

IDSA GUIDELINE

IDSA Infectious Diseases Society of America · hivma hiv medicine association · OXFORD

Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America

Tamar F. Barlam,[1] Sam E. Cosgrove,[2] Lilian M. Abbo,[3] Conan MacDougall,[4] Audrey N. Schuetz,[5] Edward J. Septimus,[6] Arjun Srinivasan,[7] Timothy H. Dellit,[8] Yngve T. Falck-Ytter,[9] Neil O. Fishman,[10] Cindy W. Hamilton,[11] Timothy C. Jenkins,[12] Pamela A. Lipsett,[13] Preeti N. Malani,[14] Larissa S. May,[15] Gregory J. Moran,[16] Melinda M. Neuhauser,[17] Jason G. Newland,[18] Christopher A. Ohl,[19] Matthew H. Samore,[20] Susan K. Seo,[21] and Kavita K. Trivedi[22]

[1]Co-Chair, Section of Infectious Diseases, Boston University School of Medicine, Boston, Massachusetts; [2]Co-Chair, Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, Maryland; [3]Division of Infectious Diseases, University of Miami Miller School of Medicine, Miami, Florida; [4]Department of Clinical Pharmacy, School of Pharmacy, University of California, San Francisco; [5]Department of Medicine, Weill Cornell Medical Center/New York–Presbyterian Hospital, New York, New York; [6]Department of Internal Medicine, Texas A&M Health Science Center College of Medicine, Houston; [7]Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia; [8]Division of Allergy and Infectious Diseases, University of Washington School of Medicine, Seattle; [9]Department of Medicine, Case Western Reserve University and Veterans Affairs Medical Center, Cleveland, Ohio; [10]Department of Medicine, University of Pennsylvania Health System, Philadelphia; [11]Hamilton House, Virginia Beach; [12]Division of Infectious Diseases, Denver Health, Denver, Colorado; [13]Department of Anesthesiology and Critical Care Medicine, Johns Hopkins University Schools of Medicine and Nursing, Baltimore, Maryland; [14]Division of Infectious Diseases, University of Michigan Health System, Ann Arbor; [15]Department of Emergency Medicine, University of California, Davis; [16]Department of Emergency Medicine, David Geffen School of Medicine, University of California, Los Angeles Medical Center, Sylmar; [17]Department of Veterans Affairs, Hines, Illinois; [18]Department of Pediatrics, Washington University School of Medicine in St. Louis, Missouri; [19]Section on Infectious Diseases, Wake Forest University School of Medicine, Winston-Salem, North Carolina; [20]Department of Veterans Affairs and University of Utah, Salt Lake City; [21]Infectious Diseases, Memorial Sloan Kettering Cancer Center, New York, New York; and [22]Trivedi Consults, LLC, Berkeley, California

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Los objetivos y sus indicadores deben responder al acrónimo

«SMART»

- ✓Específicos
- ✓Medibles
- ✓Realizables
- ✓Relevantes
- ✓Precisos en el tiempo

CEIRAS 2023

Indicadores calidad prescripción

La evaluación de la **calidad de la prescripción** de antibióticos:

- Reducción del consumo de antibióticos
- Uso de una forma más óptima

Permite comprender los patrones de uso e identificar las dianas para la intervención

GEIRAS 2023

ELSEVIER

Enfermedades Infecciosas y Microbiología Clínica

Volume 31, Supplement 4, September 2013, Pages 25-30

Evaluating the quality of antimicrobial prescribing: Is standardisation possible?

Evaluación de la calidad de la prescripción de antibióticos: ¿es posible la estandarización?

Pilar Retamar [a], M. Luisa Martín [b], José Molina [c], Alfonso del Arco [d]

Show more

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Appropriateness measures

Table 4. Final List of Quality Indicators to Monitor Antibiotic Use for All Bacterial Infections in Hospitalized Adult Patients in Non-Intensive Care Unit Departments

Number From Table 1	Quality Indicator All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection	Numerator Description All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection	Denominator Description All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection
25	Empirical systemic antibiotic therapy should be prescribed according to the local guideline. (If local guidelines are missing, prescribe according to national guideline. If national guidelines are also missing, prescribe according to international guideline.)	Number of patients who started with empirical systemic antibiotic therapy according to the local guideline	Total number of patients who started with empirical systemic antibiotic therapy
6	Before starting systemic antibiotic therapy, at least 2 sets of blood cultures should be taken.	Number of patients in whom at least 2 blood cultures were taken before systemic antibiotic therapy was started	Total number of patients who started with systemic antibiotic therapy
26	When starting systemic antibiotic therapy, specimens for culture from suspected sites of infection should be taken as soon as possible, preferably before antibiotics are started. (Cultures should be taken until a maximum of 24 h after antibiotics are started.)	Number of patients who started with systemic antibiotic therapy and in whom cultures from suspected sites of infection were taken within 24 h after the systemic antibiotics were started	Total number of patients who started with systemic antibiotic therapy
15	Empirical antibiotics should be changed to pathogen-directed therapy if culture results become available	Number of patients with empirical systemic antibiotics whose culture became positive and changing to pathogen-directed therapy was done correctly	Total number of patients with empirical systemic antibiotics whose culture became positive
14	Dose and dosing interval of systemic antibiotics should be adapted to renal function.	Number of patients with a compromised renal function with a dosing regimen adjusted to renal function (defined as eGFR <50 mL/min/1.73 m^2)	Total number of patients who started with systemic antibiotic therapy and who had a compromised renal function (defined as eGFR <50 mL/min/1.73 m^2)
27	Systemic antibiotic therapy should be switched from intravenous to oral antibiotic therapy within 48–72 h on the basis of the clinical condition and when oral treatment is adequate. Adequate: (1) when antibiotic is available orally, (2) when oral intake and gastrointestinal absorption are adequate, (3) adequate in terms of diagnosis (exceptions, eg, endocarditis, meningitis)	Number of patients with intravenous antibiotics for 48–72 h, in whom changing to oral antibiotic therapy on the basis of clinical condition was done	Total number of patients with intravenous antibiotics for 48–72 h, in whom changing to oral antibiotic therapy on the basis of the clinical condition was indicated
28	An antibiotic plan should be documented in the case notes at the start of systemic antibiotic treatment (Antibiotic plan is indication, name, doses, route, and interval of administration.)	Number of patients who started with systemic antibiotic therapy for whom an antibiotic plan was documented in the case notes	Total number of patients who started with systemic antibiotic therapy
29	Therapeutic drug monitoring should be performed when the treatment duration is >3 d for aminoglycosides and >5 d for vancomycin.	Number of these patients with at least 1 serum drug level measurement	Total number of patients who received aminoglycosides for >3 d and/or vancomycin for >5 d
30	Empirical antibiotic therapy for presumed bacterial infection should be discontinued based on the lack of clinical and/or microbiological evidence of infection. The maximum duration of empirical systemic antibiotic treatment should be 7 d.	Number of patients whose empirical antibiotic therapy was discontinued within 7 d, because of lack of clinical and/or microbiological evidence of infection	Total number of patients who started empirical systemic antibiotic therapy, but lacked clinical and/or microbiological evidence of infection

Table 4 continued.

Number From Table 1	Quality Indicator All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection	Numerator Description All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection	Denominator Description All Patients Are Adults, Admitted to a Non-ICU Department With >24 h of Systemic Antibiotics Because of a Suspected Bacterial Infection
31	A current local antibiotic guideline should be present in the hospital and an evaluation whether an update should be considered should be done every 3 y.		
32	Local antibiotic guidelines should correspond to the national antibiotic guidelines, but should deviate based on local resistance patterns.		

Abbreviations: eGFR, estimated glomerular filtration rate; ICU, intensive care unit.

GEIRAS 2025

van den Bosch CM, Geerlings SE, Natsch S, Prins JM, Hulscher ME. Quality indicators to measure appropriate antibiotic use in hospitalized adults. Clin Infect Dis. 2015 Jan 15;60(2):281-91..

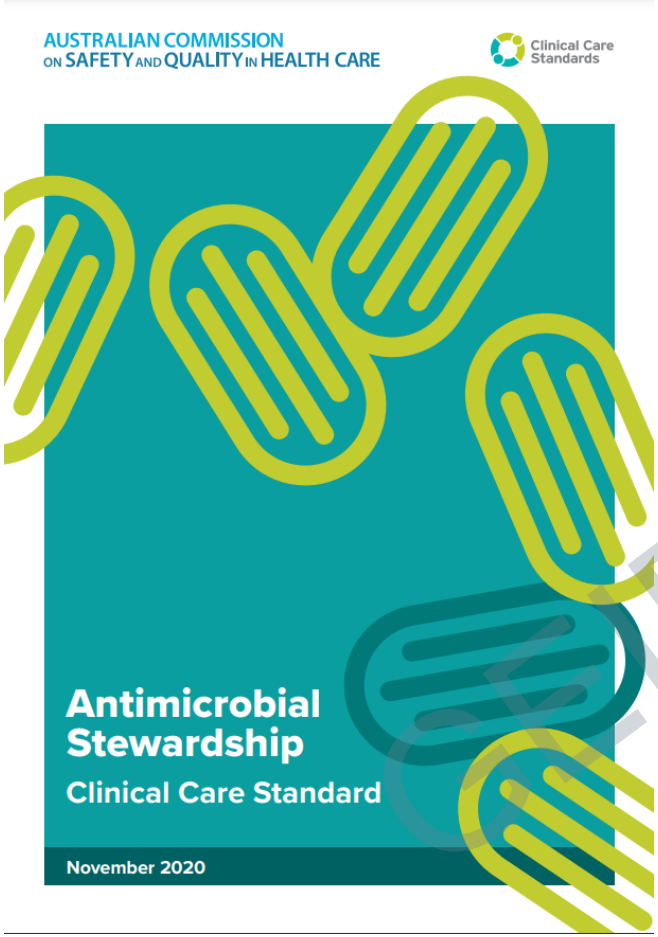
Quality indicator	Numerator[a]	Denominator
Empirical antibiotic therapy according to local guidelines	No. of patients with EAT according to local guidelines	No. of patients with EAT and clinical syndrome defined in local guidelines
Adequate request for blood cultures	No. of patients with 2 sets of blood cultures before EAT initiation	No. of patients with systemic antibiotic treatment
Adequate request for blood culture from site of infection	No. of patients with EAT and adequate request for blood culture from site of infection	No. of patients with systemic antibiotic treatment and cultivable infection
Antibiotic treatment directed to culture results	No. of patients with EAT directed to culture results	No. of patients with systemic antibiotic treatment and positive culture results with clinical significance
Sequential antibiotic therapy within 72 h	No. of patients with antibiotic treatment for ≥72 h and clinical stability with sequential antibiotic therapy	No. of patients who were candidates for sequential antibiotic therapy
Patients receiving unnecessary antibiotic treatment in the absence of clinical or microbiological evidence of infection	No. of patients with EAT receiving unnecessary antibiotic treatment in the absence of clinical or microbiological evidence on the fifth day of treatment	No. of patients with EAT for ≥5 days
Dosage adjusted for renal function	No. of patients with eGFR of <50 ml/min/1.73 m^2 and dosage adjusted for renal function	No. of patients with systemic antibiotic treatment and eGFR of <50 ml/min/1.73 m^2
TDM	No. of patients with ≥1 determination of drug concentration	No. of patients with treatment for ≥3 days with amikacin or gentamicin and/or for ≥5 days with vancomycin or targeted treatments

QIpub	Applicability (no. of patients/ total no. of patients evaluated [% [95% CI]])	Adherence (no. of patients/ total no. of patients [% [95% CI]])	Room for improvement[a] (% [95% CI])
Empirical antibiotic therapy according to local guidelines	135/362 (37.3 [32.5–42.4])	94/135 (69.6 [61.4–76.8])	30.4 (23.2–38.6)
Adequate request for blood cultures	353/362 (97.5 [95.3–98.7])	139/353 (39.4 [34.4–44.6])	60.6 (55.4–65.6)
Adequate request for culture from site of infection	269/362 (74.3 [69.6–78.5])	215/269 (79.9 [74.7–84.3])	20.1 (15.7–25.3)
Antibiotic treatment directed to culture results	106/362 (29.3 [24.8–34.2])	97/106 (91.5 [84.7–95.5])	8.5 (4.53–15.4)
Sequential antibiotic therapy within 72 h[b]	220/362 (60.8 [55.7–65.7])	114/220 (51.8 [45.2–58.3])	48.18 (41.7–54.8)
Patients receiving unnecessary antibiotic treatment in the absence of clinical or microbiological evidence[c]	254/362 (70.2 [65.3–74.7])[d]	31/254 (12.20 [8.73–16.8])	12.20 (8.73–16.8)
Dosage adjusted for renal function	68/362 (18.8 [15.1–23.1])	53/68 (77.9 [66.7–86.2])	22.1 (13.9–33.3)
TDM	22/362 (6.1 [4.10–9.03])	9/22 (40.9 [23.3–61.3])	59.1 (38.7–76.7)

Sólo el TDM QI mostró una baja tasa de aplicabilidad (6,1%)

GEIRAS 2023

Arcenillas P,et al.. Assessment of Quality Indicators for Appropriate Antibiotic Use. Antimicrob Agents Chemother. 2018 Nov 26;62(12):e00875-18..



Antimicrobial Stewardship Clinical Care Standard

Quality statements

1 Life-threatening conditions
A patient with a life-threatening condition due to a suspected infection receives an appropriate antimicrobial immediately, without waiting for the results of investigations.

2 Use of guidelines
When a patient is prescribed an antimicrobial, this is done in accordance with the current *Therapeutic Guidelines* or evidence-based, locally endorsed guidelines and the antimicrobial formulary.

3 Adverse reactions to antimicrobials
When an adverse reaction (including an allergy) to an antimicrobial is reported by a patient or recorded in their healthcare record, the active ingredient(s), date, nature and severity of the reaction are assessed and documented. This enables the most appropriate antimicrobial to be used when required.

4 Microbiological testing
A patient with a suspected infection has appropriate samples taken for microbiology testing as clinically indicated, preferably before starting antimicrobial therapy.

5 Patient information and shared decision making
A patient with an infection, or at risk of an infection, is provided with information about their condition and treatment options in a way that they can understand. If antimicrobials are prescribed, information on how to use them, when to stop, potential side effects and a review plan is discussed with the patient.

6 Documentation
When a patient is prescribed an antimicrobial, the indication, active ingredient, dose, frequency and route of administration, and the intended duration or review plan are documented in the patient's healthcare record.

7 Review of therapy
A patient prescribed an antimicrobial has regular clinical review of their therapy, with the frequency of review dependent on patient acuity and risk factors. The need for ongoing antimicrobial use, appropriate microbial spectrum of activity, dose, frequency and route of administration are assessed and adjusted accordingly. Investigation results are reviewed promptly when they are reported.

8 Surgical and procedural prophylaxis
A patient having surgery or a procedure is prescribed antimicrobial prophylaxis in accordance with the current *Therapeutic Guidelines* or evidence-based, locally endorsed guidelines. This includes recommendations about the need for prophylaxis, choice of antimicrobial, dose, route and timing of administration, and duration.

CEIRAS 2023

Farmacia Hospitalaria 2022
| Vol. 46 | N° 5 | 271 - 281 | 271

Farmacia HOSPITALARIA
Órgano oficial de expresión científica de la Sociedad Española de Farmacia Hospitalaria

ORIGINALES
Artículo bilingüe inglés/español

Estudio PAUSATE: Prevalencia y adecuación del uso hospitalario de antimicrobianos en España

PAUSATE Study: Prevalence and appropriateness of the use of antimicrobials in Spanish hospitals

José María Gutiérrez-Urbón[1], Mercedes Arenere-Mendoza[2], Edurne Fernández-de-Gamarra-Marlínez[3], Aurora Fernández-Polo[4], Silvia González-Suárez[5], Jordi Nicolás-Picó[6], María Eugenia Rodríguez-Mateos[7], Elena Sánchez-Yáñez[8]

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aceptado el 17 de enero de 2022.
Early Access date (08/02/2022).
DOI: 10.7399/fh.13152

103 hospitales

3.568 pacientes, de los que recibieron antimicrobianos 1.498 (42,0%)

De los pacientes con terapia antimicrobiana, 1.449 (96,7%) recibieron al menos un antibacteriano, 126 (8,4%) al menos un antifúngico y 80 (5,3%) al menos un antivírico.

Respecto a la adecuación del tratamiento, la prescripción fue considerada adecuada en el 34% de los casos, mejorable en el 45%, inadecuada en el 19% y no valorable en el 2%

GEIRAS 2023

Gutiérrez-Urbón JM, et al.. Estudio PAUSATE: Prevalencia y adecuación del uso hospitalario de antimicrobianos en España. Farm Hosp. 2022;46(5):271-81.

Tabla 3. Grado de adecuación por dimensiones y prescripción global

Dimensión	Grado de adecuación (%)			
Indicación de antimicrobiano	Adecuada 88%	Inadecuada 8%		Dudosa 4%
Elección del agente	Adecuada 71%	Mejorable 23%	Inadecuada 3%	Dudosa 3%
Momento de la primera dosis	Adecuada 86%	Inadecuada 6%		Dudosa 8%
Dosis y frecuencia de administración	Adecuada 87%	Mejorable 7%	Inadecuada 4%	Dudosa 2%
Vía de administración	Adecuada 89%	Mejorable 9%	Inadecuada 1%	Dudosa 1%
Duración del tratamiento	Adecuada 69%	Excesiva 19%	Corta 2%	Dudosa 10%
Monitorización de eficacia y seguridad	Adecuada 75%	Mejorable 17%	Inadecuada 4%	Dudosa 4%
Registro en la historia clínica	Completo 53%	Insuficiente 34%		Dudoso 13%
Prescripción global	**Adecuada 34%**	**Mejorable 45%**	**Inadecuada 19%**	**No valorable 2%**

GEIRAS 2023

Gutiérrez-Urbón JM, et al.. Estudio PAUSATE: Prevalencia y adecuación del uso hospitalario de antimicrobianos en España. Farm Hosp. 2022;46(5):271-81.

El principal problema de la valoración de la calidad del uso de los antimicrobianos:

- No existe un método estandarizado que contemple todas las dimensiones de la prescripción antimicrobiana y que defina el baremo de cada una de estas dimensiones y calificación de la prescripción en su globalidad.

- Variabilidad interobservador. (la subjetividad incertidumbre inherente)

GEIRAS 2023

Enferm Infecc Microbiol Clin (Engl Ed). 2023 Oct 31:S2529-993X(23)00253-8.
doi: 10.1016/j.eimce.2023.06.008. Online ahead of print.

Agreement between pharmacists and physicians on the assessment of appropriateness of antimicrobial prescribing

José María Gutiérrez-Urbón [1], Eva Campelo-Sánchez [2], Sara Cobo-Sacristán [3], Marcelo Domínguez-Cantero [4], María Victoria Gil-Navarro [5], Sonia Luque [6], María Eugenia Martínez-Núñez [7], Beatriz Mejuto [8], Francisco Moreno-Ramos [9], Leonor Periañez-Párraga [10], Carmen Rodríguez-González [11], Teresa Rodríguez-Jato [8]; members of the Pharmaceutical Care Group for Patients with Infectious Diseases (AFinf) of the Spanish Society of Hospital Pharmacy (SEFH)

Affiliations + expand

PMID: 37919198 DOI: 10.1016/j.eimce.2023.06.008

101 hospitales

411 prescripciones

- Se observó un muy buen nivel de acuerdo (AC1 > 0,80) entre farmacéuticos y médicos en todos los indicadores de calidad, excepto en la duración del tratamiento, y registro en la historia clínica.
- El acuerdo fue mayor en las unidades de cuidados críticos, oncohematología y pediatría que en las unidades médicas y quirúrgicas.

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Gestión de desabastecimientos

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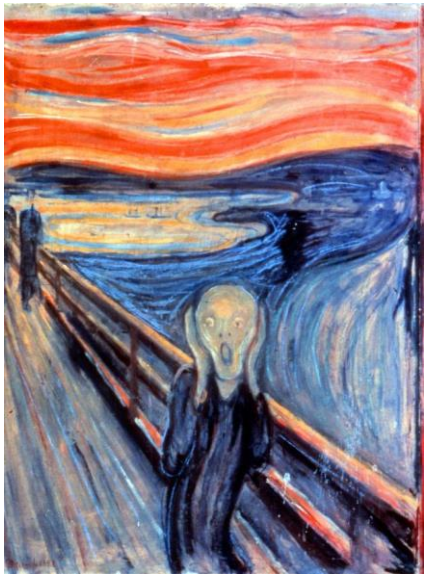
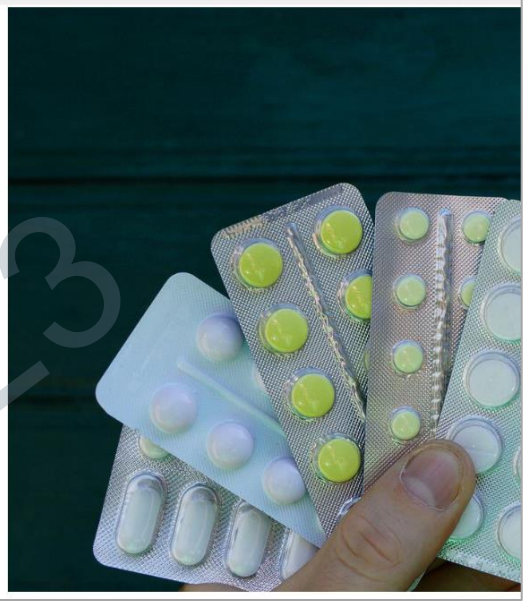


EL PAÍS — Opinión

EDITORIAL >

Escasez de medicamentos

La frecuencia del desabastecimiento de algunos productos farmacéuticos exige actuar tanto en la producción como en la distribución

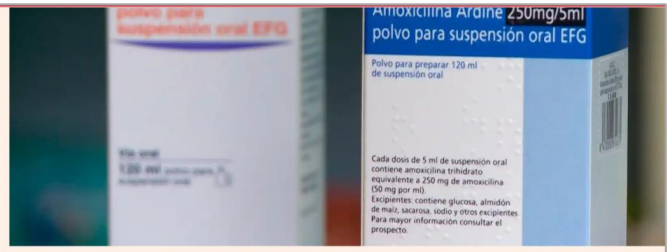


20minutos — NACIONAL

La escasez de antibióticos obliga a los padres a partir las pastillas de adultos para los tratamientos de los niños

20MINUTOS / NOTICIA / 30.01.2023 - 18:56H

- El desabastecimiento de fármacos afecta a distintos países de la Unión Europea.
- Sanidad alerta de problemas de suministro en fármacos, algunos usados contra infecciones respiratorias en niños.
- La falta de hasta 3.000 medicamentos básicos en Italia obliga a intervenir al Gobierno.



Envases de amoxicilina.

OBSERVATORIO DE LA SANIDAD

La escasez de la amoxicilina persiste: falta en 24 países de la Unión Europea, entre los que está España

En nuestro país hay 25 presentaciones con problemas de suministro.

GEIRAS 2023

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Creación en 2022 del Grupo Directivo Ejecutivo sobre Desabastecimiento y Seguridad de Medicamentos (***Executive Steering Group on Shortages and Safety of Medicinal Products, MSSG***).

Establecer recomendaciones para la implementación de acciones coordinadas a nivel de la UE en relación con los problemas de suministro de medicamentos, además de monitorizar el suministro y la demanda de medicamentos considerados críticos.

GERAS 2023

Comisión Europea también ha puesto en marcha una acción conjunta para mejorar el problema de la escasez de medicamentos propuesta por la Dirección General de Salud y Seguridad Alimentaria (SANTE), a través del Plan de Trabajo 2021 del Programa EU4Health (2021-2027): ***Coordination and Harmonisation of the Existing Systems against Shortages of Medicines, European Network*** **(Chessmen)**.

La AEMPS lidera una de las ocho acciones enfocada a determinar las causas raíz que originan los problemas de suministro y armonizar las definiciones relativas a estos problemas

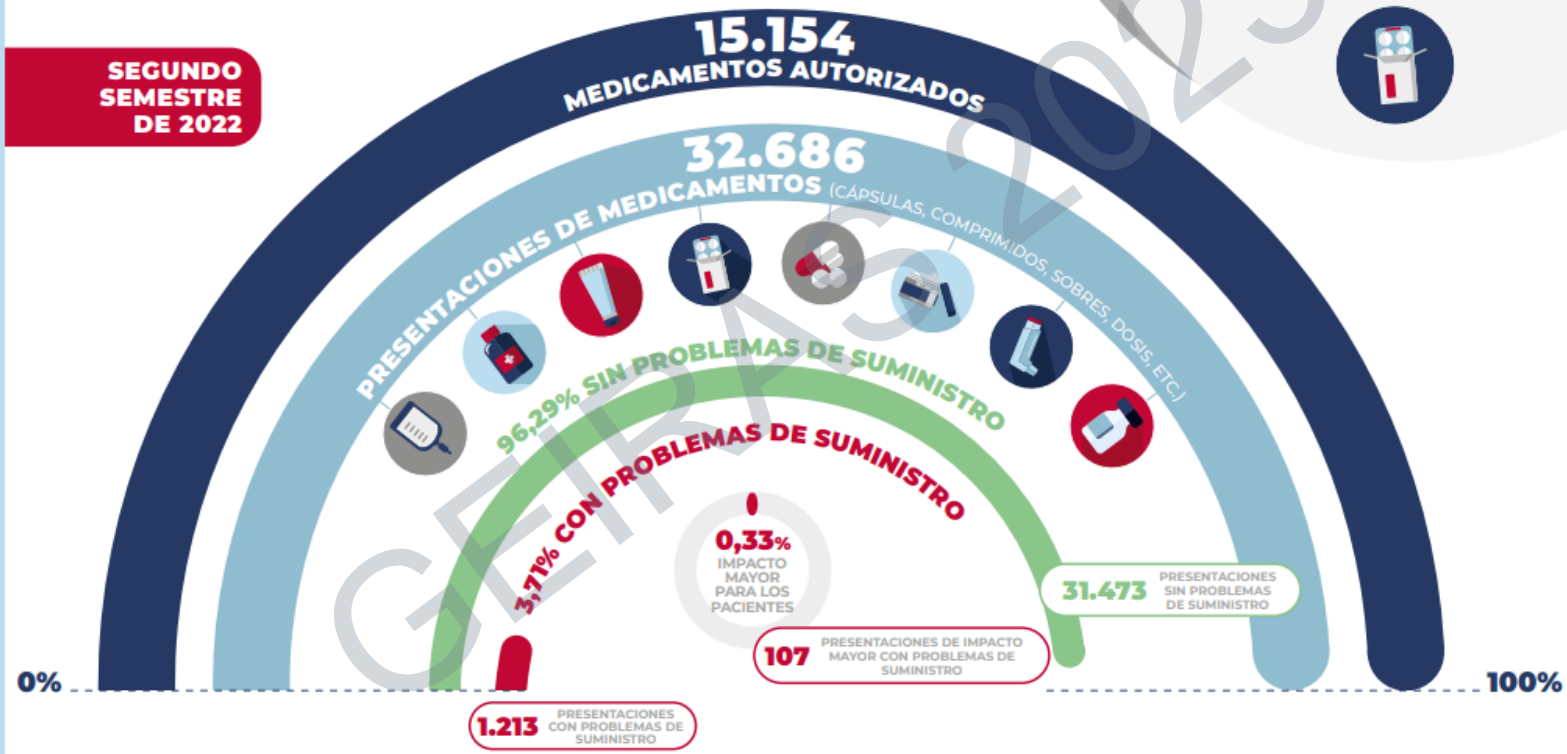
GERAS 2023

¿Qué impacto tienen en el paciente los problemas de suministro?

Los problemas de suministro se miden en presentaciones de medicamentos

Ejemplo

El **ibuprofeno** puede encontrarse en diferentes presentaciones como comprimido, cápsula o jarabe



GEIRAS 2023

•**Niveles de impacto**:

- **Impacto nulo (nivel 0)**: el impacto se considera nulo cuando, debido a la corta duración del problema de suministro, se mantiene un abastecimiento normal del medicamento a los pacientes con las unidades existentes en el canal de distribución. En caso de medicamentos que se suministran o dispensan a nivel hospitalario el problema de suministro pasa a tener nivel de impacto 1. Estos expedientes no se publican en CIMA.
- **Impacto menor (nivel 1)**: se considera menor cuando, al existir en el mercado otros medicamentos comercializados con el mismo principio activo y la misma vía de administración, es posible la sustitución del medicamento por el profesional farmacéutico en la mayoría de los casos. Estos expedientes se publican en CIMA como "Existe/n otro/s medicamento/s con los mismos principios activos y para la misma vía de administración", "Existe/n otro/s medicamento/s con el mismo principio activo y para la misma vía de administración" o "La AEMPS ha autorizado unidades por comercialización excepcional".
- **Impacto medio (nivel 2)**: se considera esta categoría cuando, existiendo alternativas en el mercado, se requiere de la intervención del médico prescriptor que debe determinar la elección de tratamientos alternativos. Estos problemas de suministro se publican en CIMA como "El médico prescriptor deberá determinar la posibilidad de utilizar otros tratamientos comercializados" o "Suministro solo a hospitales".
- **Impacto mayor**: en esta categoría, la falta del medicamento genera un impacto asistencial importante, por no disponer de alternativas terapéuticas en alguna o ninguna de sus indicaciones, siendo necesarias acciones que van más allá de la sustitución del medicamento por el profesional farmacéutico o el cambio de prescripción por parte del profesional médico. Dentro del impacto mayor existen encontramos dos niveles:
  - **Nivel 3**: se publican en CIMA como "Se puede solicitar como medicamento extranjero", "Consultar Nota Informativa" o "El titular de autorización de comercialización está realizando una distribución controlada al existir unidades limitadas".
  - **Nivel 4**: se publican en CIMA como "Desabastecimiento temporal".

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GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

cima

ESPAÑOL ENGLISH

HOME QUÉ ES CIMA NOMENCLÁTOR GLOSARIO Iniciar sesión

883 RESULTADOS

PARA LA BÚSQUEDA
PROBLEMAS DE SUMINISTRO ACTIVOS

EXPORTAR

¿Qué es un problema de suministro?

Fecha de inicio | Fecha de fin | Código nacional | Nombre

Filtro de resultados

Nombre

Con problemas de suministro...

- [x] Activos
- [ ] Resueltos

COD. NACIONAL
770404

FECHA PREVISTA DE INICIO
12/12/2023

FECHA PREVISTA FINALIZACIÓN
-

DIEMIL SOLUCION, 1 frasco de 180 ml

El médico prescriptor deberá determinar la posibilidad de utilizar otros tratamientos comercializados. Existen otros medicamentos comercializados que contienen el principio activo piracetam.

COD. NACIONAL
660707

FECHA PREVISTA DE INICIO
12/12/2023

FECHA PREVISTA FINALIZACIÓN
29/02/2024

TERBINAFINA PENSA 250 mg COMPRIMIDOS EFG, 28 comprimidos

Existe/n otro/s medicamento/s con el mismo principio activo y para la misma vía de administración.

COD. NACIONAL
815563

ACICLOVIR KERN PHARMA 800 mg COMPRIMIDOS DISPERSABLES EFG, 35 comprimidos

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https://cima.aemps.es/cima/publico/listadesabastecimiento.html

- Escasez de materias primas
- Lotes del medicamento que no cumplen con las especificaciones
- Retrasos logísticos, incluidos los posibles impactos de eventos globales.

CEIPAS 2023

Causa de los problemes de suministro

- Problemas de capacidad de la planta (31,0%)
- Problemas de fabricación no derivados de problemas de calidad (22,8%)
- Aumento de la demanda (20,4%)

GEIRAS 2023

https://cima.aemps.es/cima/publico/listadesabastecimiento.html

Managing Antimicrobial Shortages

Communicate, collaborate and share decision making

Pharmacist

- Review stock and usage
- Prepare a local strategy with prescribers
- Consider alternative:
  - Brands
  - Strengths
  - Formulations
  - Antimicrobial/s
  - SSSI*
  - Access pathways (e.g. SAS*)
- Consider impacts on alternative medicines
- Refer to strategy when a patient presents a prescription
- Dispense appropriate antimicrobial/s and counsel patient

Patient/consumer

Prescriber

- Provide contact details to pharmacist
- Prepare a local strategy with pharmacist
- Consider an alternative therapy
- Seek expert advice if required
- Prescribe appropriate antimicrobial/s and counsel patient

Continue to collaborate when normal supply resumes

GEIRAS 2023

https://www.safetyandquality.gov.au/publications-and-resources/resource-library/antimicrobial-shortages-clinician-guidance

Inicio > Acciones informativas > Notas informativas > La Unión Europea intensifica las medidas para evitar el próximo invierno posibles problemas de suministro de antibióticos

CEIRAS 2025

- **Aumentar ahora la producción de antibióticos esenciales**:

- **Supervisión de la oferta y la demanda**

- **Conciencia pública y uso prudente**: los antibióticos deben usarse con prudencia para mantener su eficacia y evitar la resistencia a los antimicrobianos. Los antibióticos solo deben recetarse para tratar infecciones bacterianas..

Muchas gracias

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GEIRAS 2023

Vall d'Hebron
Barcelona Hospital Campus