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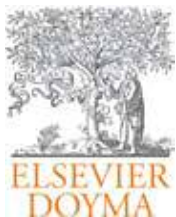
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ORIGINAL ARTICLE

Quality of the pharmacotherapeutic recommendations for the integrated care procedures in Andalusia

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Abstract

Objectives: To evaluate the quality of the pharmacotherapeutic recommendations included in the Integrated Care Processes (PAIs regarding its initials in Spanish) of the Andalusian Ministry of Health, published up to March 2008, through the design and validation of a tool.

Methods: The assessment tool was designed based on similar instruments, specifically the AGREE. Other criteria included were taken from various literature sources or were devised by ourselves. The tool was validated prior to being used. After applying it to all the PAIs, we examined the degree of compliance with these pharmacotherapeutical criteria, both as a whole and by PAIs subgroups.

Results: The developed tool is a questionnaire of 20 items, divided into 4 sections. The first section consists of the essential criteria, and the rest make reference to more specific, non essential criteria: definition of the level of evidence, thoroughness of information and definition of indicators. It was found that 4 of the 60 PAIs do not contain any type of therapeutic recommendation. No PAI fulfils all the items listed in the tool, however, 70 % of them fulfil the essential quality criteria established.

Conclusions: There is a great variability in the content of pharmacotherapeutical recommendations for each PAI. Once the validity of the tool has been proved, it could be used to assess the quality of the therapeutic recommendations in clinical practice guidelines.

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PALABRAS CLAVE

Procesos asistenciales;
Directrices para la planificación en salud;
Recomendaciones farmacoterapéuticas;
Evaluación de servicios sanitarios

Calidad de las recomendaciones farmacoterapéuticas de los procesos asistenciales integrados en Andalucía

Resumen

Objetivos: Evaluar, a través del diseño y la validación de una herramienta, la calidad de las recomendaciones farmacoterapéuticas incluidas en los Procesos Asistenciales Integrados (PAI) de la Consejería de Salud de la Junta de Andalucía, publicados hasta marzo de 2008.

Métodos: La herramienta de evaluación se diseñó a partir de instrumentos similares, fundamentalmente el Appraisal of Guidelines for Research and Evaluation. Otros criterios incluidos provenían de diversas fuentes bibliográficas o fueron de elaboración propia. Previamente a su utilización, la herramienta fue validada. Tras la aplicación a todos los PAI, se analizó el grado de cumplimiento de estos criterios farmacoterapéuticos globalmente y por subgrupos de PAI.

Resultados: La herramienta elaborada consiste en un cuestionario de 20 ítems dividido en 4 bloques. El primer bloque corresponde a criterios esenciales, el resto hace referencia a criterios más específicos y considerados no esenciales: definición del nivel de evidencia, exhaustividad de la información y definición de indicadores. De los 60 PAI, 4 no contienen ningún tipo de recomendación terapéutica. Ningún PAI cumple el total de ítems recogidos en la herramienta; no obstante, un 70 % de ellos cumple los criterios esenciales de calidad establecidos.

Conclusiones: Hay una gran variabilidad en cuanto al contenido de recomendaciones farmacoterapéuticas de cada PAI. Una vez demostrada la validez de la herramienta diseñada, podría utilizarse para valorar la calidad de las recomendaciones terapéuticas en guías de práctica clínica.

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Introduction

Organising medical assistance by means of clinical channels, protocols or other tools is a constant process that is found in many health services in Western countries.¹ Examples include the Scottish Intercollegiate Guidelines Network² and the Guidances of the National Institute for Health and Clinical Excellence³ in the United Kingdom, the Health Care Order Set from the Institute for Clinical System Improvement⁴ in the United States, the *Linee Guida Aziendali of Istituto Superiore di Sanità* in Italy,⁵ the mini-HTA (Health Technology Assessment) of the Danish Centre for Evaluation and Health Technology Assessment in Denmark,⁶ the MUMM programme (Managed Uptake of Medical Methods) in Finland,⁷ the Consensus Conference Guidelines of the *Haute Autorité de Santé* in France,⁸ the General Guidelines for Assessing, Approving & Introducing New Procedures into a Hospital or Health Service of the College of Surgeons of Australia and New Zealand (Australia)⁹ or the Handbook for the Preparation of Explicit Evidence-Based Clinical Practice Guidelines (New Zealand).¹⁰

In Andalusia, the Regional Ministry of Health has chosen integrated care processes (PAI) as its model. Process management in the Andalusian public health system (SSPA) is an instrument used to analyse the many components involved in providing health services with a view to organising work flows, integrating up-to-date knowledge and placing a certain emphasis on the results obtained. It therefore keeps users' and professionals' expectations in mind, and attempts to decrease the variability of professionals' actions in order to reach a reasonable degree

of homogeneity. In this way, we can offer users high-quality health care services.¹¹

The SSPA has placed a special emphasis on implementing integrated care processes, particularly with regard to recommendations' applicability and force from a global standpoint. However, according to our knowledge to date, their pharmacotherapeutic recommendations have not been evaluated.

Although they were not created to be clinical practice guides (CPG) as such, it is important to evaluate the incorporation of the concept of rational use of a drug as one of its quality guidelines, since the management of that medication may be assisted or harmed by the way these general strategic concepts are defined.¹²

The purpose of this study was to evaluate the quality of pharmacotherapy recommendations for all PAIs published by the Andalusian Regional Ministry of Health as of March 2008.

Methods

We identified all integrated care processes published on the Andalusian Regional Ministry of Health's Web page as of March 2008.

We decided to design our own instrument for designing pharmacotherapy recommendations, since no adequate instruments could be found in a preliminary bibliographical search. This tool consists of a simple checklist to evaluate qualitative aspects, such as the presence or absence of recommendations, their compliance with the evidence-

based medicine paradigm, formal and methodological factors and the presence or absence of indicators. In addition, it will also be useful for measuring quantitative differences between integrated care processes (exhaustiveness of the recommendations).

When designing the questionnaire, the research team had the help of a panel of experts consisting of seven specialists in hospital pharmacy with experience in pharmacotherapy and pharmaceutical care in different departments (internal medicine, surgery, psychiatry, respiratory medicine, otorhinolaryngology, and oncology).

Items on the questionnaire were either based on a simplified, adapted form of the AGREE tool (Appraisal of Guidelines for Research and Evaluation)¹³ and a tool designed by the FUINSA task force on therapeutic guides,¹⁴ or else they were elaborated by the panel of experts. All criteria were designed for dichotomous answers.

Before criteria were used, an evaluation was carried out to consider their pertinence, capacity for differentiation, reproducibility and written description. The questionnaire was independently applied to four randomly-selected processes in two different rounds (scheduled one week apart). This was done by the 4 main researchers for the 4 chosen processes, and then a concordance analysis was run for the results gathered by each of the researchers (kappa index). Constant values higher than 0.7 were considered acceptable.

Once the validation had been made, 2 independent evaluators applied the questionnaire to all of the integrated care processes that were available at the start of the study. Discrepancies were resolved by means of the consensus of the entire research team.

We performed a descriptive statistical analysis for the frequency with which one criterion was met for all processes (percentage of the processes that comply with each of the criteria) as well as for the frequency with which the set criteria were met in each process (percentage of items that are met out of the list of total items).

The processes were subsequently grouped according to field, and the general analysis was repeated for each field. The assigned fields were: medical, surgical and other (having to do with prevention or diagnosis). In addition, the medical field was divided into specialties: these were assigned according to the task force that had designed each process.

Results

The finished questionnaire contained a total of 20 items classified into 4 basic blocks: essential criteria, evidence level definition, exhaustiveness of the information, and indicator definition (Table 1).

The 4 processes chosen at random for internal validation of the tool were the following: hip arthroplasty, breast cancer, pulmonary thromboembolism, and non-ST elevation acute coronary syndrome. Table 2 lists the results from the concordance analysis.

A total of 60 integrated care processes were identified for the study; of this total, 43 processes were assigned to the medical field, 12 to the surgical field, and 5 to "other."

For the total set, mean compliance for the total items

was 9.8 out of 20. The median value was 9.5 (interquartile range, 6-14).

With regard to the essential criteria block on the questionnaire, 42 of the 60 integrated care processes contained recommendations for more than half of the clinical examples, and 14 had a recommendation for at least one example. Only 4 processes were accompanied by no recommendations.

With respect to the second block (evidence level definition), only 10 processes indicated the evidence level for more than half of their recommendations; 12 processes indicated it for at least one recommendation; and 38 never indicated the evidence level.

The mean for criteria met in the "exhaustiveness of information" block was 6.1 out of that block's total of 13 items. Indicators were included in 27 of the 60 processes (45%).

Table 3 shows the questionnaire's degree of compliance for each of the individual processes.

None of the integrated care processes met all of the items listed in the instrument, and 4 contained no pharmacotherapy recommendations whatsoever.

Table 4 shows the percentage of the processes in which each one of the criteria is fulfilled. The criteria that were met the least were the one referring to bibliographical references for more than half of the pharmacotherapeutical recommendations (7 of the 60 processes), followed by the one referring to a pharmacological algorithm (8 processes).

Table 5 shows the analysis of the number of criteria the questionnaire met based on the field to which each PAI belongs.

The study broken down by fields shows that the percentage of the criteria (essential or non-essential) is higher in medical PAIs than in surgical PAIs. Within the medical field, the processes assigned to the cardiology specialty had the highest degree of compliance, with a mean of 13 out of 20 criteria (data not shown).

Discussion

As PAIs constitute one of the main strategies for improving care quality and proper integration of up-to-date scientific knowledge in Andalusia, we would hope that they would incorporate correct drug use as a basic strategy toward decreasing variability in the resources used and results obtained.¹⁵ In this respect, nearly all of the PAIs included pharmacotherapy recommendations, and 70% included them for most clinical examples. This may be considered a satisfactory quantitative result.

However, the formal quality of these recommendations is poorer, although we must point out that we only studied the formal structure of the PAIs' pharmacotherapy recommendations, and not their validity and congruence with scientific evidence. For this reason, this study does not begin to evaluate this last question, although it should be a necessary requirement for ensuring the suitability of a recommendation.¹⁶

Very few PAIs earn high scores for all of the formal quality components that we considered in our evaluation. In particular, only a few PAIs indicate the evidence level

Table 1. Criteria included in the evaluation tool used in the present study

Item	Explanation in our tool	Source	Original wording
Essential criteria			
Does it contain treatment recommendations?	Answer yes if there is at least one recommendation	Own source	
Does it contain treatment recommendations for most clinical examples?	Answer yes if pharmacotherapy recommendations are present for more than half of the examples. Examples are considered to be those clinical situations or patient groups that are clearly set apart in the process due to their aetiology, histology, comorbidity, prognosis or other variables	Own source	
Defining evidence level			
Does it indicate the level of evidence for a recommendation?	Answer yes if there is at least one reference	AGREE ¹³	Criteria for selecting evidence are clearly described
Does it indicate the level of evidence for most recommendations?	Answer yes if there are references in more than half of the recommendations as described above	AGREE ¹³	Criteria for selecting evidence are clearly described
Does it provide references for its recommendation(s)?	Answer yes if at least one pharmacological recommendation can be linked to a reference	AGREE ¹³	An explicit relationship exists between each of the recommendations and the evidence upon which they are based
Does it provide references for most of its recommendations?	Answer yes if more than half of the recommendations can be linked to at least one bibliographic reference	AGREE ¹³	An explicit relationship exists between each of the recommendations and the evidence upon which they are based
Exhaustiveness of the information			
Do the recommendations list specific drugs?	Answer yes if at least one recommendation is listed	Own source	
Are guidelines for dosage, administration frequency, and treatment duration provided?	Answer yes if at least one recommendation is listed	Moreno et al ¹⁴	It lists specific recommendations for each treatment, giving alternatives, dosage and duration range where applicable, and patient groups in which the treatment is indicated or contraindicated
Are first-choice and alternative medications listed?	Answer yes if at least one recommendation is listed. Drugs of choice are understood to be such due to reasons of effectiveness/safety or cost-effectiveness	AGREE ¹³	The different options for treating the disease or condition are clearly presented

(Continued on next page)

Table 1. Criteria included in the evaluation tool used in the present study*(Continuation)*

Item	Explanation in our tool	Source	Original wording
Are some medications or medication groups specifically advised against?	Answer yes if there is at least one recommendation of this type due to reasons of effectiveness/safety or cost-effectiveness	Moreno et al ¹⁴	It lists specific recommendations for each treatment, giving alternatives, dosage and duration range where applicable, and patient groups in which the treatment is indicated or contraindicated
Does it list drugs for specific patient subgroups or special clinical situations? RF LF Pregnancy	Answer yes if the recommendations (whether they are the same or personalised) consider pharmacotherapy broken down by different clinical situations. In particular, evaluators should look for renal failure, liver failure or pregnancy (if applicable) as the most generally pertinent situations	Moreno et al ¹⁴	Clearly define the health problems covered by the guide: a) Types of health problems; b) If possible comorbidities or the evolving phase of the different problems are considered; c) If it considers physiopathological or clinical circumstances that might influence or change the choice of the proposed treatments for different health problems
Does it specify different treatments for different states of the same disease?	Answer yes if there are different therapeutic recommendations for different diagnostic or prognostic categories	Moreno et al ¹⁴	Clearly define the health problems covered by the guide: a) Types of health problems; b) If possible comorbidities or the evolving phase of the different problems are considered; c) If it considers physiopathological or clinical circumstances that might influence or change the choice of the proposed treatments for different health problems
Is a goal defined in order to evaluate the effectiveness of the pharmacotherapy?	An analytical value, a functional level or a certain score on a subjective scale. This refers to the entire process or its main morbidity, ex. mortality, change in functional state, decrease in hospitalisations, normalisation of CD4 levels, improved glycosylated haemoglobin	Own source	

(Continued on next page)

Item	Explanation in our tool	Source	Original wording
Does it define a follow-up method to check the effectiveness of a recommended drug?	A follow-up method that helps us detect the effectiveness of each treatment, ex. VAS score for pain, INR for thromboembolic prophylaxis, etc	Own source	
Are possible adverse reactions defined?	Answer yes if they are listed for at least those cases in which adverse reactions are known for their frequency or severity	AGREE ¹³	The recommendations were written with a view to health benefits, side effects and risks
Does it define methods for preventing, minimising, or communicating adverse reactions to the drug?	Ex. Use of paracetamol to alleviate flu-like symptoms of interferon 2b	Own source	
Are drug-drug, drug-food, and drug-diagnostic test interactions considered?	Answer yes if at least the most well-known interaction cases are listed	Own source	
Does it mention non-pharmacological treatment alternatives?	Answer yes if there is at least one recommendation of this type	AGREE ¹³	The different options for treating the disease or condition are clearly presented
Does it define a pharmacological treatment algorithm?	Answer yes if there is at least one specific algorithm for pharmacotherapy. General algorithms in which one of the outcomes mentions pharmacological treatment are not included	Moreno et al ¹⁴	Consider whether listing recommendations is based on tools that facilitate their understanding and use in clinical practice
Indicator definition			
Are indicators defined in order to evaluate proper use of medications in the care process?	Answer yes if at least one indicator directly related to pharmacotherapy appears	AGREE ¹³	The guide offers a list of key criteria with a view to performing follow-up or auditing
AGREE indicates Appraisal of Guidelines for Research and Evaluation; INR, international normalised ratio. VAS, visual analogue scale.			

and the bibliographic references for the pharmacotherapy recommendations. This fact does not mean that the recommendations are not suitable; rather, it probably means that the PAI's methodology instructions did not prioritise references as an indispensable component. While lack of references is really a format problem, it does subtract a great deal of credibility from the recommendations.

In contrast, relevant factors, such as indicating dosage guidelines, selecting first-choice over alternative drugs and the mention of non-pharmacological alternatives are present in most PAIs. We should mention that differentiating between first-choice and alternative treatments is a judgment call for the PAI authors, and one which frequently does not appear in other documents. Prioritising certain medications over others due to reasons involving the risk/benefit relationship, the best available evidence or the cost-effectiveness ratio is a process of evaluating and deciding

between alternatives. This requires proper methodology and rigorous analysis. Lastly, the high frequency with which non-pharmacological alternatives are included points toward the progress made in demedicalising many care processes, in keeping with demand in recent years.¹⁷⁻¹⁹

On the other hand, factors having to do with the inclusion of recommendations on interactions and how to minimise adverse reactions have a low compliance rate; this may be due to the complexity of these subjects and their scarce mention in clinical practice guidelines. The low rate of inclusion for an algorithm in the treatment recommendations is less understandable, as this is a very useful decision-making tool, in addition to being a way of synthesising recommendations that is very relevant to the structure of the PAIs themselves.

Only half of the PAIs include evaluation indicators for following pharmacotherapy recommendations, which shows

Table 2. Internal validation of questionnaire

Process	Evaluator 2	Evaluator 3	Evaluator 4
Non-ST elevation acute coronary syndrome			
Evaluator 1	$\kappa=0.945$	$\kappa=0.835$	$\kappa=0.835$
Evaluator 2		$\kappa=0.891$	$\kappa=0.891$
Evaluator 3			$\kappa=1$
Pulmonary thromboembolism			
Evaluator 1	$\kappa=0.944$	$\kappa=0.864$	$\kappa=0.864$
Evaluator 2		$\kappa=0.823$	$\kappa=0.823$
Evaluator 3			$\kappa=1$
Breast cancer			
Evaluator 1	$\kappa=1$	$\kappa=0.938$	$\kappa=0.938$
Evaluator 2		$\kappa=0.938$	$\kappa=0.938$
Evaluator 3			$\kappa=1$
Hip arthroplasty			
Evaluator 1	$\kappa=1$	$\kappa=0.8$	$\kappa=0.8$
Evaluator 2		$\kappa=0.8$	$\kappa=0.8$
Evaluator 3			$\kappa=1$

Note: from a statistical viewpoint, concordance is thought to be good where kappa value >0.7 .

just how little importance is given to this aspect of PAI development.

With respect to analysis by area, as we might have expected, the highest percentage of compliance with criteria corresponded to the medical field rather than the surgical field, due to the differing roles of pharmacotherapy in these fields. With regard to results broken down by medical specialty, the cardiology data stand out; although they score higher than the rest, as a total, they barely reach a 65% compliance level for all of the criteria (mean of compliance levels for the 8 processes pertaining to this specialty).

Several published studies are available which evaluate CPGs in Spain, although they do not specifically address pharmacotherapy recommendations. In general, they state that the formal quality of CPGs in Spain is low, as shown by our results.

Capdevilla et al²⁰ use the AGREE tool to evaluate several CPGs for some of the most common care processes in the area of the Commission of Medicine and Specialties related to the Catalan Council of Health Science Specialties, Regional government of Catalonia (*Generalitat*). Only one of the 12 reviewed CPGs had a score of higher than 50% for all areas covered by the instrument. Graham et al²¹ also used an adaptation of the AGREE tool to evaluate the quality of a set of CPGs published in Canada in 1998. Their results were better than ours, but this could be due to 2 reasons: firstly, their quality assessment was overall, and not of just the treatment recommendations, and secondly, because in our case, we were examining the CPGs. In a 2004 study, Navarro Puerto et al²² analysed the quality of 61 Spanish CPGs using the AGREE tool and found that, except for the areas of scope and independence, the vast majority received scores below 50% in the other areas.

We were unable to find a questionnaire that was completely suited to the objectives of this study in the published literature. First of all, the AGREE tool is the assessment tool of reference for CPGs, but it is not designed to specifically assess pharmacotherapy recommendations, and it is difficult to adapt it for use with other types of protocols such as PAIs.²³ Likewise, other tools listed by Rico et al²⁴ in their review of different criteria for evaluating CPGs were not applicable to our study. The project by the FUINSA study group, on the other hand, does establish detailed assessment criteria for pharmacotherapy guidelines, but it is not completely applicable to our project's objective, which is to evaluate pharmacotherapy recommendations found within broader guides.¹⁴ However, as stated above, this project and the AGREE tool were essential precedents for the creation of our own questionnaire.

We therefore opted for elaborating a specific questionnaire in which the authors established certain criteria, which may be the main weakness of our study. However, before the criteria were applied, we validated them with help from a panel of experts, which may have decreased their subjectivity. Among the included criteria, we find some that were considered of particular importance, and we included them twice in order to evaluate both their qualitative and quantitative contributions; the purpose of this step was to set apart the PAIs that did not comply with a certain criterion at all. In addition, we evaluated excellence for guides that complied with at least half of the guidelines, thereby selecting processes that considered most of the criteria.

We did not consider AGREE criteria having to do with the guide's overall objective and patient description and participation in the guide (guide's clinical objectives, clinical aspects covered in the guide and the patients for whom the CPG is intended) because these are very general topics. Although sharing a decision with the patient is an increasingly important component of a quality treatment recommendation, we feel that including this factor in the assessment would complicate the analysis excessively. Other criteria from the AGREE tool that were not included were those referring to clarity and presentation; we consider these matters as secondary to the main purpose of our study.

On the other hand, it is true that the low number of PAIs which met some of these criteria (such as the existence of a pharmacological algorithm, the definition of methods for preventing or predicting adverse reactions or description of potential interactions) may demonstrate that definitions on our side were excessively strict. Also, the inclusion of more criteria on non-pharmacological alternatives could have permitted a better score for surgical processes and those in the "other" category (preventative or diagnostic).

Another possible limitation of our study can be found in the analysis by area and medical specialty. PAIs are inherently designed to be multi-disciplinary and multi-level, and for this reason, assigning each PAI to a specific area and specialty could in many cases have been imprecise and dependent on the evaluators' judgment.

PAIs are fundamental tools for organising integration of primary and specialist care, placing the patient at the centre of the system and describing the best possible practice for integrated care of patients with defined morbidity processes

Table 3. Number of criteria met by each integrated care process

Processes	All criteria (n=20) No. (%)	Essential criteria	Evidence level definition, %	Exhaustiveness of the information (n=13) No. (%)	Indicator definition	Specialty
Anaemia	16 (80)	Mainly	25	12 (92)	Yes	Family medicine
Stable angina (chest pain)	11 (55)	Mainly	25	7 (54)	Yes	Cardiology
Anxiety depression, somatisation disorders	2 (10)	Occasionally	0	1 (8)	No	Family medicine
Arrhythmias	15 (75)	Mainly	75	11 (85)	Yes	Cardiology
Knee and hip osteoarthritis	16 (80)	Mainly	75	13 (100)	Yes	Rheumatology
Adult asthma	15 (75)	Mainly	75	11 (85)	Yes	Pneumology
Childhood asthma	15 (75)	Mainly	100	9 (69)	Yes	Paediatrics
Cerebrovascular event	15 (75)	Mainly	75	9 (69)	Yes	Neurology
Care for patients with multiple illnesses	1 (5)	Occasionally	0	0	No	Internal medicine
Severe trauma care	0	Occasionally	0	0	No	Family medicine
Cervix/uterus cancer	8 (40)	Occasionally	50	5 (38)	No	Gynaecology
Skin cancer	10 (50)	Mainly	75	5 (38)	No	Dermatology
Skin cancer	9 (45)	Mainly	25	6 (46)	No	Oncology
Headaches	6 (30)	Mainly	0	4 (31)	No	Neurology
Palliative care	0	None	0	0	No	Family medicine
Dementia	11 (55)	Mainly	50	7 (54)	No	Neurology
Diabetes mellitus type 1	11 (55)	Mainly	0	8 (62)	Yes	Endocrinology
Diabetes mellitus type 2	11 (55)	Mainly	0	8 (62)	Yes	Endocrinology
Dysphonia	2 (10)	Occasionally	0	1 (8)	No	Otorhinolaryngology
Thyroid dysfunction	10 (50)	Mainly	0	8 (62)	No	Endocrinology
Dyspepsia	15 (75)	Mainly	25	12 (92)	Yes	Family medicine
Abdominal pain	6 (30)	Mainly	0	3 (23)	Yes	Family medicine
Non-oncological chronic pain	14 (70)	Mainly	25	11 (85)	No	Internal medicine
Generic (unaffiliated) chest pain	7 (35)	Mainly	0	4 (31)	Yes	Cardiology
Pregnancy, childbirth and postpartum	5 (25)	Occasionally	0	4 (31)	No	Gynaecology
Chronic obstructive pulmonary disease	15 (75)	Mainly	50	10 (77)	No	Pneumology
Fibromyalgia	8 (40)	Mainly	0	5 (38)	Yes	Family medicine
Intermediate-length fever	7 (35)	Occasionally	25	4 (32)	Yes	Infectious diseases
Abnormal uterine haemorrhaging	11 (55)	Mainly	50	6 (46)	Yes	Gynaecology
Viral hepatitis	13 (65)	Mainly	50	8 (62)	Yes	Digestive
Benign prostate hypertrophy. Prostate cancer	12 (60)	Mainly	25	9 (69)	No	Urology
ST-elevation AMI (chest pain)	15 (75)	Mainly	50	9 (69)	Yes	Cardiology
Heart failure	14 (70)	Mainly	50	9 (69)	Yes	Cardiology
Otitis media	12 (60)	Mainly	50	7 (54)	Yes	Paediatrics
Vascular risk	18 (90)	Mainly	100	11 (85)	Yes	Family medicine

(Continued on next page)

Table 3. Number of criteria met by each integrated care process (Continuation)

Processes	All criteria (n=20) No. (%)	Essential criteria	Evidence level definition, %	Exhaustiveness of the information (n=13) No. (%)	Indicator definition	Specialty
Acute aortic syndrome (chest pain)	8 (40)	Mainly	0	6 (46)	No	Cardiology
Non-ST elevation acute coronary syndrome (NSTACS); unstable angina and non-ST elevation myocardial infarction (AI/NSTEMI) (chest pain)	18 (90)	Mainly	50	13 (100)	Yes	Cardiology
Childhood fever syndrome	13 (65)	Mainly	50	8 (62)	Yes	Paediatrics
Severe mental disorder	16 (80)	Mainly	75	11 (85)	No	Psychiatrics
Eating disorders	7 (35)	Mainly	0	5 (38)	No	Psychiatrics
Kidney replacement therapy for chronic kidney disease: dialysis and kidney transplant	15 (75)	Mainly	100	9 (69)	No	Nephrology
Pulmonary thromboembolism (chest pain)	12 (60)	Mainly	25	8 (62)	Yes	Cardiology
HIV/AIDS	15 (75)	Mainly	25	11 (85)	Yes	Infectious diseases
Surgical field						
Tonsillectomy/ adenoidectomy	6 (30)	Mainly	25	2 (15)	Yes	
Hip arthroplasty	12 (60)	Mainly	50	7 (46)	Yes	
Colorectal cancer	10 (50)	Mainly	25	7 (46)	No	
Cataracts	1 (5)	None	0	1 (8)	No	
Chronic venous insufficiency	2 (10)	Occasionally	0	1 (8)	No	
Cholelithiasis/ cholecystitis	0	None	0	0	No	
Broken hip in elderly patient	10 (50)	Occasionally	75	6 (46)	No	
Abdominal wall hernia	4 (20)	Occasionally	25	2 (15)	No	
Heart transplant	11 (55)	Mainly	0	9 (46)	No	
Pancreatic transplant	11 (55)	Mainly	0	9 (69)	No	
Hepatic transplant	3 (15)	Occasionally	0	2 (15)	No	
Lung transplant	5 (25)	Occasionally	0	9 (69)	No	
Other processes						
Care for dental caries and dental inclusions	6 (30)	Occasionally	0	5 (38)	No	
Care for smokers	14 (70)	Mainly	50	9 (69)	Yes	
Early care	3 (15)	Occasionally	0	2 (15)	No	
Breast cancer. Early detection of breast cancer	7 (35)	Mainly	0	5 (38)	No	
Network of Andalusian tumour banks		None	0	0	No	

AMI indicates acute myocardial infarction; HIV, human immunodeficiency virus.

Table 4. Percentage of integrated care processes (PAI) that fulfil each criterion by field

Criteria	All PAIs, % (n=60)	Medical field, % (n=43)	Surgical field, % (n=12)	Other, % (n=5)
Essential criteria				
Does it contain treatment recommendations?	92	95	83	80
Does it contain treatment recommendations for most examples?	70	81	42	40
Defining evidence level				
Does it indicate the level of evidence for a recommendation?	37	44	25	0
Does it indicate the level of evidence for most recommendations?	17	23	0	0
Does it provide references for any of its recommendations?	47	53	33	20
Does it provide references for most of its recommendations?	12	12	8	20
Exhaustiveness of the information				
Do the recommendations list specific drugs?	85	88	83	80
Are guidelines for dosage, administration frequency and treatment duration provided?	78	86	67	60
Are first-choice and alternative medications listed?	68	77	42	60
Are some medications or medication groups specifically advised against?	38	49	17	0
Does it list drugs for specific patient subgroups or special clinical situations? RF LF Pregnancy	33	37	25	20
Does it specify different treatments for different states of the same disease?	57	70	17	40
Is a goal defined in order to evaluate the effectiveness of the pharmacotherapy?	45	56	17	20
Does it define a follow-up method to check the effectiveness of a recommended drug?	42	51	17	20
Are possible adverse reactions defined?	38	42	33	20
Does it define methods for preventing, minimising or communicating adverse reactions to the drug?	18	21	17	0
Are drug-drug, drug-food and drug-diagnostic test interactions considered?	28	28	25	20
Does it mention non-pharmacological treatment alternatives?	73	74	67	80
Does it define a pharmacological treatment algorithm?	15	19	8	0
Indicator definition				
Are indicators defined in order to evaluate proper use of medications in the care process?	45	56	17	20

using common, shared language. As with any broad-reaching management intervention, it was impossible for this study to cover all aspects equally. It is possible that formal rigour in pharmacotherapy recommendations was not one of the main organisational priorities in their early days.²⁵

However, the results of our study show that there is a need to review these recommendations, and as we were finishing the editing process for this article, such a process was already being implemented on an institutional level by the Regional Ministry of Health.²⁶

Lastly, we believe that the questionnaire we prepared for this study can also be applied to evaluating pharmacotherapy

recommendation quality in other treatment guides and protocols in various health districts and systems.

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Table 5. Analysis of the degree of compliance of processes by clinical field

Clinical field	All criteria (n=20)	Essential criteria (n=2)	Evidence level definition (n=4)	Exhaustiveness of the information (n=13)	Definition of indicators (percentage of processes with indicators) ^a
Medical processes					
Mean	11.2 ^b	1.8	1.3	6.9	56
Mean	11	2	1	8	
Interquartile range	7-15	2-2	0-2	4.5-10	
Surgical processes					
Mean	6.2	1.3	0.44	4.2	17
Mean	5.5	1	0	3	
Interquartile range	2.6-10	1-2	0-1	1.5-7	
Others					
Mean	6	1.2	0.4	4.6	20
Mean	6	1	0	5	
Interquartile range	1.5-6.5	0.5-2	0-0	2-5	
Total					
Mean	9.8	1.6	1.5	6.1	45
Mean	9.5	2	1	7.5	
Interquartile range	6-14	1-2	0-1	4.5-9	

^aThere is no reason to analyse central tendency parameters where n=1.

^bMean criteria met compared to total criteria (n).

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References

- Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technology Assessment*. 2004;8:1-84.
- Scottish Intercollegiate Guidelines Network (SIGN) [Internet site]. Edimburgo: published guidelines; c2001-08 [Updated January 31, 2009] [Accessed February 4, 2009]. Available from: <http://www.sign.ac.uk/guidelines>
- National Institute for Health and Clinical Excellence (NICE) [Internet site]. London: Guidance by type; c2007 [Updated January 7, 2009] [Accessed January 23, 2009]. Available from: <http://www.nice.org.uk/Guidance/Type>
- Institute for Clinical System Improvement (ICSI) [Internet site]. Bloomington: Health Care Guidelines: order sets; c2001-08 [Updated December 11, 2007] [Accessed January 23, 2009]. Available from: http://www.icsi.org/guidelines_and_more/order_sets/
- Sistema Nazionale Linee Guida – Istituto Superiore di Sanità [Internet site]. Roma: Linee guida nazionali; c2009 [Updated January 26, 2009] [Accessed February 4, 2009]. Available from: <http://www.pnlg.it/>
- The national Board of Health. Introduction to mini-HTA: a management and decision support tool for the hospital service [Internet publication]. Copenhagen: The national Board of Health; 2005. [Accessed January 23, 2009]. Available from: http://www.sst.dk/publ/Publ2005/CEMTV/Mini_MTV/Introduction_mini-HTA.pdf
- Kaila M. Managed uptake of medical methods. Finohta newsletter [Internet publication]. February 2007 [Accessed December 12, 2008_ 2:12-13. Available from: http://fi.nohta.stakes.fi/NR/rdonlyres/2872CE40-7E60-400C-9CAD-FC1466378B11/0/impakti2007_2.pdf
- Haute Autorité de Santé. Les conférences de consensus - base méthodologique pour leur réalisation en France [Internet publication]. Saint-Denis: Haute Autorité de Santé; 2008. [Accessed January 23, 2009]. Available from: http://www.has-sante.fr/portail/jcms/c_431285
- The College of Surgeons of Australia and New Zealand. General Guidelines for Assessing, Approving & Introducing New Procedures into a Hospital or Health Service [Internet publication]. Melbourne: Royal Australasian College of Surgeons; 2008. [Accessed December 10, 2008]. Available from: <http://www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/ASERNIPSPublications/Guidelines>
- New Zealand Guidelines Group. Handbook for the preparation of explicit evidence-based clinical practice guidelines [Internet publication]. Wellington: New Zealand Guidelines Group; 2003. [Accessed November 23, 2008]. Available from: <http://www.nzgg.org.nz/index.cfm?fuseaction=download&fusesubaction=template&libraryID=102>
- Consejería de Salud de la Junta de Andalucía [Internet site]. Sevilla: Procesos Asistenciales Integrados; c2007 [Updated April 1, 2008] [Accessed April 2, 2008]. Available from: <http://www.csalud.junta-andalucia.es/procesos/>
- Segú JL. Gestión de los medicamentos en los sistemas de salud. La perspectiva de la microgestión. En: Meneu R, Peiró S, editores. Elementos para la gestión de la prescripción y prestación farmacéuticas. Barcelona: Masson-Elsevier; 2004. p. 173-221.
- The AGREE collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care*. 2003;12:18-23.

14. Moreno A y grupo de trabajo FUINSA sobre Guías Terapéuticas. Directrices para el desarrollo y la evaluación de guías terapéuticas: elementos y recomendaciones para su diseño y elaboración. *Med Clin (Barc)*. 2007;128:100-10.
15. Wolf S, Grol R, Hutchinson A, Eccles M, Grinshaw J. Potential benefits, limitations, and harms of clinical guidelines. *BMJ*. 1999; 318:527-30.
16. Watine J. Guidelines are never perfect; however they need to be transparent. *Clin Chim Acta*. 2007;381:184-5.
17. Orenstein SR, McGowan JD. Efficacy of conservative therapy as taught in the primary care setting for symptoms suggesting infant gastroesophageal reflux. *J Pediatr*. 2008; 152:310-4.
18. Schneiderman J. Non-pharmacologic strategies in hematopoietic stem cell transplantation. *Curr Pharm Des*. 2008;14:1987-96.
19. Adams ML, Arminio GJ. Non-pharmacologic pain management intervention. *Clin Podiatr Med Surg*. 2008;25:409-29.
20. Capdevilla JA, Gavagnach M, Martínez S, Torres A. Evaluación crítica de las guías de práctica clínica. *Med Clin (Barc)*. 2008; 130:376-9.
21. Graham ID, Beardall S, Carter AO, Glennie J, Hebert PC, Tetroe JM, et al. What is the quality of drug therapy clinical practice guidelines in Canada? *CMAJ*. 2001;165:157-63.
22. Navarro Puerto MA, Ruiz Romero F, Reyes Domínguez A, Gutiérrez Ibarluzea I, Alonso Ortiz del Río C, Hermosilla Gago T, et al. ¿Las guías que nos guían son fiables? *Rev Clin Esp*. 2005;11:533-40.
23. The AGREE Collaboration. AGREE Instrument Spanish version [Internet publication]. 2001 [Accessed January 23, 2009]. Available from: <http://www.agreecollaboration.org/pdf/es.pdf>
24. Rico R, Gutiérrez-Ibarluzea I, Asua J, Navarro MA, Reyes A, Marín I, et al. Valoración de escalas y criterios para la evaluación de guías de práctica clínica. *Rev Esp Salud Publica*. 2004;78:457-67.
25. Consejería de Salud. GUÍA de diseño y mejora continua de procesos asistenciales: calidad por sistema. [Internet publication]. Sevilla; 2001. [Accessed November 23, 2008]. Available from: http://www.juntadeandalucia.es/salud/contenidos/profesionales/procesos/libro_completo.pdf
26. Consejería de salud. El uso racional de los recursos farmacoterapéuticos [Internet document]. Sevilla: 7.º encuentro sobre Procesos Asistenciales Integrados; 2008. [Accessed February 7, 2009]. Available from: <http://www.juntadeandalucia.es/salud/contenidos/procesos/presentaciones/3.%20El%20uso%20racional%20de%20los%20recursos%20farmacoterapeuticos.pdf>