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ORIGINAL ARTICLE

Analysis of the selection process for new drugs in a tertiary hospital 2004-2007

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Abstract
Objective: The purpose of this study is to describe the structure of the CFyT, the Pharmacy and Therapeutics Committee, and a tertiary hospital's selection process for new drugs.
Material and methods: All annals of the PTC and the New Drug Incorporation Guides (GINF) to incorporate new drugs received at Hospital Virgen del Rocío between 2004 and 2007 were reviewed. We carried out a descriptive study which collected variables having to do with the drug (drug type, type of register, route of administration and legal category), the petitioner (responsible division, professional category and request type) and the result of the evaluation (final decision, elapsed time between the request and the decision).
Results: Of the 72 requested drugs, 45 (62.5%) were approved: six as equivalent treatments, 36 (80%) with specific recommendations, and three (4.2%) with no restrictions. Twelve drugs (81.1%) were not included due to insufficient evidence of their effectiveness compared with the current treatment. The most frequently-requested drug type was the antineoplastics, most commonly requested by Oncology and Haematology divisions. We highlight the fact that many of the petitioners included clinical trials (97.2%) and data referring to costs (84.7%).
Conclusions: There is a high level of compliance with the GINF guide in our centre, which guarantees that the P&TC's final decision is based on scientific evidence.

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PALABRAS CLAVE
Guía para la Incorporación de Nuevos Fármacos;
Selección;
Nuevos medicamentos;
Comisión de Farmacia y Terapéutica;
Guía Farmacoterapéutica

Análisis del proceso de selección de nuevos medicamentos en un hospital terciario. Años 2004-07

Resumen
Objetivo: Describir la estructura de la Comisión de Farmacia y Terapéutica y el proceso de selección de nuevos medicamentos de un hospital terciario.
Material y métodos: Se revisan todas las actas de la Comisión de Farmacia y Terapéutica y las Guías para la Incorporación de Nuevos Fármacos recibidas en el periodo 2004-2007 en el Hospital Universitario Virgen del Rocío. Se realiza un estudio descriptivo que recoge variables relacionadas con el fármaco (grupo terapéutico, vía de registro, vía de administración y categoría legal), con el solicitante (servicio al que pertenece, categoría profesional y tipo de petición) y con el resultado de la evaluación (decisión final adoptada y tiempo de retraso entre la petición y la decisión).
Resultados: De los 72 medicamentos solicitados, se aprobaron 45 (62,5%), 6 como equivalentes terapéuticos, 36 (80%) con recomendaciones específicas y 3 (4,2%) sin ninguna restricción. De los fármacos no incluidos, en 12 (81,1%) fue por insuficiente evidencia de su eficacia comparada con el tratamiento actual. El grupo terapéutico solicitado con más frecuencia fue el de los antineoplásicos, destacando Oncología y Hematología entre los peticionarios. Destaca el alto porcentaje de solicitantes que aportaron ensayos clínicos (97,2%) y datos referentes al coste (84,7%).
Conclusiones: Existe un alto grado de cumplimentación de la Guía para la Incorporación de Nuevos Fármacos en nuestro centro que garantiza una decisión final por parte de la Comisión de Farmacia y Terapéutica basada en la evidencia científica.

Introduction

The European Union policy on drug registration does not allow evaluation of new medications in the context of the rest of the existing alternatives, which obliges hospitals to perform their own evaluations.[1,2] This function falls to the responsibility of the Pharmacy and Therapeutic Commissions (PTC).[3] The final decision of whether or not to incorporate a medication into use at a hospital and the establishment of conditions of its use, in the case of inclusion, must be made under regulated procedures based on an analysis of the available evidence.[4]

In spite of the coincidence between the various institutions regarding the criteria that are used to evaluate the medications and tools to be used, an appreciable level of variability between the decisions adopted by the PTCs at different hospitals has been identified.[5-7]

This variability could be due to the disparities between the tools used in the selection process for medications and the differences in clinical practice that could implicate differences in equality and accessibility of certain treatments.[8] Therefore, it is necessary to use standardised tools (application guides, evaluations, and work protocols). It is also necessary to evaluate the validity of these tools, their level of implantation and completion, as well as product quality.

In an earlier publication by our group, the PTC activity at our hospital was evaluated along with the implantation of the Guide for Incorporation of New Drugs (GINF) during the 2002-2003 period.[9] Other studies have evaluated the implantation of other tools,[10] such as the report model established in 2005 by the GENESIS group.[11]

The objective of this study was to describe the structure of the PTC and the selection process for new medications in a tertiary hospital during the 2004-2007 period.

Material and methods

We performed a descriptive analysis of the characteristics for the process of application and decision making of the PTC at the Virgen del Rocío University Hospital, based on a previous article published by our group.[9]

The study sample was made up of all of the applications for incorporation of new medications received in the PTC during the period of 2004-2007. The commission reviews all of the available drugs at the hospital, including relevant compassionate use and foreign drugs, works in accordance with a standardised protocol that complies with standard principals.[12,13] and is based primarily on two instruments: the GINF request guide[14] and the GENESIS evaluation report.

We identified all of the medications that requested an evaluation during this period through the PTC. For each drug, variables related to the medication (therapeutic group, method of registration and administration, and legal category), with the petitioner (professional affiliation, professional category, sex, and type of request), and with the GINF request (one variable for each of the questions on the questionnaire not previously covered).

Our study variables were the same as those that appear on the questionnaire for compliance by the petitioner. As a result, the variables collected for each medication were: therapeutic group according to the first digit in the ATC

code or the official Spanish Anatomical, Therapeutic, and Chemical Classification System; the registry system according to the current situation at the time of evaluation was termed "centralised" or "mutual recognition" (EMEA agency) "national", "compassionate use" or "foreign medication"; route of administration was termed "parenteral", "oral", or "other"; the legal category of the medication was termed as "hospital use", "hospital diagnosis", "master formula", "foreign medication", "prescription" or "other" according to the situation that is finally adopted by our country for each.

The professional category of the petitioner was labelled as "department head", "section chief", "area specialty faculty (ASF)", or "internal medicine resident", and the type of request was labelled as "individually titled", "consensus among colleagues", or "consensus among colleagues and department head".

The variables related to the GINF questionnaire were defined as they appeared in the case of closed questions, and as dichotomous in the case of open questions with the answer "yes" corresponding to full compliance and "no" when the question was not filled.

Furthermore, variables related to the process and results of the PTC evaluation were collected for each medication (final decision adopted and time of delay between the request and decision), as well as for the effort made by the commission stratified by year (number of meetings, assistants, attendees, points taken from the daily record, and medications evaluated). The decision finally adopted by the PTC was classified according to the specific decision made using the options proposed by the GINF as a baseline.

All of the data was compiled and coded by two researchers working together, following the same criteria and coming to a consensus in the case of discrepancies. For each of the variables, we performed a simple descriptive statistical analysis using the normal distribution using SPSS software version 15.

We established as a primary result the rates of drug acceptance, analysing their distribution according to various strata considered to be relevant: category and clinical department of the petitioner, therapeutic group, and registry system for the drug.

Regarding the quality evaluation for GINF compliance, we considered 5 different possible results: 1) coincidence of the indication requested with the officially approved method in Spain as an index for "off-label" requests; 2) indication or lack thereof for current alternative treatment as a differentiation key for evaluation in the hospital PTCs considering the evaluation of the regulating agencies; 3) inclusion of clinical trials as a basic element of quality control; 4) inclusion of costs as an assessment of the level of clinician involvement in the economic analysis,[15] and 5) the inclusion of the previously determined number of patients to be treated as an element of quality control for the analysis of costs and health impact. The level of compliance of these conditions, apart from the GINF, was analysed using the same strata of interest previously outlined.

We performed a comparative analysis with a similar study performed in 2002-2003 with the objective of studying the temporal evolution of the principal variables.[9]

Results

Over the course of the study period, 72 requests for incorporation of a new drug were evaluated. The characteristics of the medications, petitioner, and request are shown in Tables 1 and 2. The number of requests increased progressively throughout the years, passing from 9 in 2004 to 26 in 2007.

The therapeutic groups for which we received the greatest number of requests were from the digestive group (A), antineoplastics (L), central nervous system (N), and various (V). This being a hospital study, the medications for parenteral administration and for hospital use or diagnosis made up the majority. More than half of the requests corresponded to medications registered for a centralised procedure.

Table 1 Characteristics of the drugs requested for evaluation at the Virgen del Rocío University Hospital between the years 2004 and 2007

Characteristic	n	%
Year of request		
2004	9	12.5
2005	16	22.2
2006	21	29.2
2007	26	36.1
Treatment group		
A	10	13.9
B	6	8.3
C	5	6.9
J	6	8.3
L	14	19.4
N	13	18.1
V	11	15.3
Others	7	9.7
Administration route		
Parenteral	35	48.6
Oral	31	43.1
Other	6	8.3
Legal type		
H	38	55.8
DH	7	9.7
Foreign	3	4.2
Prescription	24	33.3
Registry type		
National	21	29.2
Mutual recognition	4	5.6
Centralised	42	58.3
Foreign medication	2	2.8
Compassionate use	3	4.2
Total	72	100

A indicates digestive group; L, antineoplastics; N, central nervous system; V, various.

Table 2 Characteristics of the requests and petitioners for new drugs at the Virgen del Rocío University Hospital (2004-2007). Level of compliance/adequacy with the format of the GINF guide

Characteristic	n	%
Petitioners		
Sex		
Males	62	13.9
Females	10	86.1
Professional category		
Head of Department	25	34.7
Head of Division	13	18.1
ASF	33	45.8,
Resident	1	1.4
Department		
Oncology	15	20.8
Haematology	10	13.9
Other Medical Departments	29	40.3
Surgical department	9	12.5
General services	9	12.5
Requests		
Level of consensus		
Individual	3	4.2
Consensus among colleagues	3	4.2
Consensus among colleagues and the department head	53	73.6
Not indicated	13	18.1
Other		
Indicates other interested departments	41	56.9
Details the advantages of the new drug	71	98.6
Total	72	

ASF indicates area specialty faculty.

In the distribution by department of the petitioner, the medical field represented 75% of the total, and the departments of Oncology and Haematology stood out as the principal requesting departments for new drugs, summing 34% of the total between the two of them. The majority of requests were endorsed and agreed on with the head of the department. The majority of petitioners were male (86.1%).

Of the 72 drugs evaluated, 45 were accepted for inclusion in the hospital pharmaceutical guide (62.5%) and the rest were dismissed. Of the medications included, 6 (13%) were considered to be therapeutic equivalents and 36 (80%) were approved with restrictions or specific recommendations for use. The final classification adopted for the use of each of the individual drugs is outlined in Table 3.

The distribution of the approved medications with regard to the non-approved drugs varied by the principal characteristics of the requests, petitioners, and drugs themselves. Table 4 demonstrates that in all of the departments, the percentage of drugs approved was greater than those not approved, except for in Oncology, where there was a greater percentage of non-approved drugs (66.6%). By therapeutic group, the greatest proportion of approved drugs corresponded to antimicrobials (all requests were included), and the lowest proportion was in the medications from group N (analgesics and mental health medications), where only 38.5% of requests were approved. Except for in this group, the percentage of approved drugs was greater than the non-approved. Half of the antineoplastics were approved.

The results regarding level of compliance with the GINF are summarised in Table 5. The points with the highest level of compliance were those related to the description of the drug and its indications, fulfilled in more than 90% of requests, although the inclusion of a protocol for therapeutic use was fulfilled in only 14% of them. Ninety-two point seven percent of requests included at least one pivotal clinical trial. However, two of these (gadobutrol and gadobenic acid) stand out as having not been included in any. The majority of requests (52.8%) estimated that the new medication would partially replace the anterior therapeutic alternative.

With respect to the quality of the work done in the PTC, the most relevant characteristics were that the mean time passed between the date of GINF submission by the petitioner and the decision made by the PTC was 118±78 days, that is, a mean of almost 4 months. However, the median value was 92 days, which does not give weight to extreme values. Such was the case for ertapenem (306 days) (maximum value), while in other medications evaluated, such as nimotuzumab, the decision was resolved in the same month as the arrival of the request.

In Table 6, other characteristics of the functioning of the PTC not related to the variables regarding the drug or request are summarised.

Table 7 shows the variation in the principal indicators of the present study with respect to a similar study performed by our group in the 2002-2003 period. In spite of a strong increase in the number of drugs evaluated annually between the two periods, the characteristics of the requests and petitioners stand out as being practically constant except for a 25% drop in requests coming from the medical field. It is also relevant to point out the decrease in percentage of medications accepted as a percentage of the total number of requests, as well as the slight drop in the rates of medications declared as being therapeutic equivalents. Among the variables that indicate quality in the GINF registry, the substantial increase in all those that presented low levels of compliance in the first round stands out, as well as the fact that the petitioners continue to submit medications without a protocol.

Discussion

This study evaluated the activity of the PTC at a hospital that is considered important for its size and complexity. With respect to the descriptions of the requests received, the number of medications evaluated has increased substantially through the years, a fact that is not due to an increase in number of medications commercialised in our country in this period, which has remained stable,[16] but

Table 3 Final classification adopted by the PTC for evaluated medications

GINF class	Drug		n (%)
No Included (37.5%)			
A2	Ezetimibe		1 (1.4)
B1	Carglumic acid	Olanzapine i.m.	13 (18.1)
	Citicoline	Pegaptanib	
	Duloxetine	Pregabaline in neuropatic pain	
	Ectainiscidine	Rifaximin	
	Fondaparinux	Ziconotide	
	Gadobutrol	Ziprasidone i.m.	
B2	Fotemustine	Nevibolol	2 (2.8)
C1	Bevacizumab in breast cancer	Sodium mycophenolate	11 (15.3)
		Nimotuzumab	
	Buprenorphine	Oxycodone	
	Eplerenone	Paricalcitol	
	Erlotinib	Sunitinib	
	Glycol/sodium bicarbonate/NaCl/KCl	Vinorelbine (oral)	
Included (62.5%)			
C2	Adalimumab	Insulin detemir	6 (8.3)
	Emtricitabine	Levo-bupivacaine	
	Infliximab	Peg-filgastrim	
D	Hexyl-aminolevulinate	Fulvestrant	36 (50)
	Aprepitant	Gadofosveset	
	Aripiprazole	Laronidase	
	Atazanavir	Lenalidomide	
	Atorvastatin	Levodopa/carbidopa	
	Azacitidine	Miglustat	
	Bivalirudin	Sodium oxybate	
	Bortezomib	Nitric oxide	
	Candesartan	Nitrous oxide/oxygen	
	Cetuximab	Parecoxib	
	Cinacalcet	Pemetrexed	
	Cisatracurium	Ranibizumab	
	Liposomal cytarabine	Sitaxentan	
	Darunavir	Sustained release tacrolimus	
	Entecavir	Tetrahydrobiopterin	
	Ertapenem	Tigecycline	
	Etanercept	Valsartan	
	Fibrinogen/thrombin	Idnocyanine green	
E	Gadobenic acid	Superparamagnetic iron	3 (4.2)
	Cysteamine		

A2 indicates not included in the GFT due to indication in a pathology that does not require hospital attendance or attention at an external patient centre; B1, not included in the GFT due to insufficient evidence for a better relation of efficiency and safety compared to the actual treatment in place at the hospital; B2, not in the GFT because the existing evidence indicates a worse profile for efficiency and security with respect to the current treatment used at the hospital; C1, the medication is similar in efficacy and safety compared to the available alternatives for the proposed indications. Furthermore, it provides no improvement in the cost-effectiveness profile, nor in the organisation or management of services, therefore, it is not included in the GFT; C2, the medication is efficient and safe, comparable to the existing alternatives for the proposed indications. Furthermore, it provides no improvement in relation to cost-effectiveness. As a result, we have included the current options as therapeutic equivalents in the guide, and so the exact drug that exists in each moment will be that which results from the public procedure of acquisition; D, included in the GFT with specific recommendations; E, included in the GFT with specific recommendations; GINF, New Drug Incorporation Guides.

perhaps due to the greater proportion of medications for commercial hospital use during this period or reasons related to the implementation of the GINF guide. This guide became mandatory at the commencement of the study period. The greater familiarity of the clinicians with this tool has influenced the increase in requests, as well as the fact that the producing laboratories reacted by offering hospital guides, possibly written in their departments, on information as has been published elsewhere.[17] In a similar manner, these factors have been able to provide an

Table 4 Distribution of the percentage of drugs included according to characteristics of the requests and drugs

Strata	Included n (%)	Excluded n (%)
Professional category of the petitioner		
Head of Department	16/25 (64.0%)	9/25 (36.0%)
Head of Department	5/13 (38.4%)	8/13 (61.5%)
ASF	23/33 (69.9%)	10/33 (30.3%)
Resident	1/1 (100.0%)	0/1 (0.0%)
Department		
Oncology	5/15 (33.3%)	10/15 (66.6%)
Haematology	6/10 (60.0%)	4/10 (40.0%)
Medical specialties	21/29 (72.4%)	8/29 (27.6%)
Surgical specialties	8/9 (88.9%)	1/9 (11.1%)
General services	5/9 (55.5%)	4/9 (44.4%)
Therapeutic group		
A	6/10 (60%)	4/10 (40.0%)
B	4/6 (66.6%)	2/6 (33.3%)
C	3/5 (60.0%)	2/5 (40.0%)
J	6/6 (100.0%)	0/6 (0.0%)
L	7/14 (50.0%)	7/14 (50.0%)
N	5/13 (38.5%)	8/13 (61.0%)
V	8/11 (72.7%)	3/11 (27.3%)
Others	6/7 (85.7%)	1/7 (14.3%)
Registry type		
National	10/21 (47.6%)	11/21 (52.4)
Mutual recognition	1/4 (25.0%)	3/4 (75.0%)
Centralised	31/42 (73.8%)	11/42 (26.2%)
Foreign medication	1/2 (50.0%)	1/2 (50.0%)
Compassionate use	2/3 (66.6%)	1/3 (33.3%)

A indicates digestive group; ASF, area specialty faculty; L, antineoplastics; N, central nervous system; V, various.

Table 5 Characteristics of GINF compliance for all requests

Strata	n	%
Description and indications		
Describes an indication approved in Spain	68	94.4
Describes a requested indication	72	100
Both coincide	66	91.7
Indicates current treatment	66	91.7
Includes current protocol	10	13.9
Efficiency, effectiveness, and safety		
Includes a CCT	70	97.2
Includes other studies	39	54.2
Includes a systematic review	26	36.1
Costs		
Includes the cost of the new drug	61	84.7
Indicates no. patients/year	53	73.6
Health impact		
Total replacement	7	9.7
Partial replacement	38	52.8
Total addition	4	5.6
Partial addition	9	12.5
Others	14	19.4
Patients attended on admission	13	18.1
Patients susceptible to be attended at a day hospital	30	41.7
Walking patients	21	29.2
Others	8	11.1

improvement in the indexes of compliance throughout the years. The characteristics of the medications evaluated are within expectations and practically have not changed throughout the years. The requests were dominated by prescription medications or those for exclusive hospital use, the therapeutic groups where these predominate (with the exception of the high frequency of requests for medications with CNS action where non-hospital drugs are the majority), medications for parenteral administration, and those with centralised registration. Indeed, said medications are those that reach the highest percentages of acceptance, although it is worth pointing out that our hospital has been characterised in recent years for not including some medications for hospital use in their pharmaceutical guide (due to comparative efficacy and cost-effectiveness) and as such, these could not be used in the health field.

Similarly, our PTC stands out as working primarily to evaluate the requests from medical departments, especially Oncology and Haematology. This situation makes it imperative to ensure specific training for the members of the PTC and those responsible for the elaboration of reports on the differential aspects of cancer pharmacotherapy, for example in the design of clinical trials in the establishment of clinical significance and cost-effective measures, etc.

The profile of the typical petitioner is a male with or without management responsibilities, primarily in the medical field, and who develops the request after a process of reaching a consensus in his department. From the management point of view, it would seem important that the person responsible for the department develop the requests for new medications. However, given the necessary involvement of the clinician in the GINF guide compliance for the PTC hearing, it is preferable that the clinician who directly attends these patients be responsible for the request.

The variation in the percentage of accepted requests with respect to the various categories analysed also followed along with the expected results. Here the high levels of general acceptance stand out, probably as a result of the fact that the medications requested are already a selection of commercialised products, the relatively high percentage of medications included as therapeutic equivalents stemming from the higher level of experience and documentation regarding how to approach this criteria, and the general acceptance of the conditions for use, probably derived from the small marginal benefit and high cost of new medications.

For some groups such as the antimicrobials or therapeutic group V medications, the rate of acceptance was very high. In the first case, it was perhaps due to the long tradition at our hospital to circumscribe the requests for antimicrobials to few clinical departments with clear criteria for evaluation, such as infectious diseases, haematology, or intensive care. In the second case, the medications included in group V, comprised of radiological contrasts for MRI, immunosupressors, and anti-TNF, are drugs that are highly valuable for the hospital. For medications with CNS action, many of these applied in psychiatry, and those for oncology or the digestive system, the rate of rejection was higher. The reason for the low percentage of inclusion of anti-cancer medications, being one of the groups with the highest demand, might be due to the fact that these drugs provide marginal benefits in terms of survival or quality of life,

Table 6 Other characteristics of the PTC functioning during the study period

	2004	2005	2006	2007	Total (mean/year)
No. meetings	9	7	10	10	36 (9)
Meeting attendance					
Mean	6.3	8.6	11	9.7	
Median	7	8	10	10	
Maximum and minimum	5-10	6-13	8-14	5-12	
No. of external invited people	18	19	21	25	83 (20.7)

Table 7 Temporal variation in the principal indicators from the current study with respect to the previous work by the same group

Variable	2002-2003	2004-2007	Variation
Population			
Requests/year, mean	16	18	+12.5%
Drugs/year, mean	13	18	+38.5%
Drugs			
Hospital use, %	53.8%	52.8%	−1%
Hospital diagnosis, %	11.5%	9.7%	−1.8%
Prescription, %	30.8%	33.3%	+2.5%
Parenteral presentation, %	56.2%	48.6%	−7.6%
Petitioners and requests			
Gender, % males	87.5%	86.1%	−1.4%
Department heads, %	37.5%	34.7%	−2.8%
Section chiefs, %	28.0%	18.1%	−9.9%
Requests from the medical fields, %	65%	40.3%	−24.7%
Oncology requests, %	15%	20.8%	+5.8%
Evaluation results			
Acceptance No. (%)	19 (73.0%)	46 (62.5%)	−10.5%
Acceptance without restrictions No. (%)	1 (3.8%)	3 (4.2%)	+0.4%
Acceptance with restrictions No. (%)	14 (53.8%)	36(50.0%)	−3.8%
Accepted as equivalents No. (%)	4 (15.4%)	6 (8.3%)	−7.1%
Time between GINF submission and Commission decision			
Mean	65±46 days	118±78	+53
Maximum	110 days	306	+196
Minimum	18 days	Same month	
Quality of registry in the GINF guide			
EC descriptions, %	72%	97.2%	+25.2%
Protocol provided, %	12%	13.9%	+1.9%
Estimated no. patients/year, %	56%	73.6%	+17.6%
Costs provided, %	50%	84.7%	+34.7%

GINF indicates New Drug Incorporation Guides.

while their cost exponentially multiplies that of the available alternatives, as has been identified by other authors for new anti-cancer drugs approved by the EMEA.[18,19]

The generally positive results in the response to the GINF tool imply that this has been incorporated into the health routines with complete normality. These indicators improve over the years and have significant differences with respect to the previous study performed by our group, which took place at the onset of the GINF implantation. As is explicitly put in the design,[13] this instrument maintains a tension between requesting essential information for decision making and high-quality information, since the majority of petitioners comply with the essential sections while other points remain rarely fulfilled.

With respect to the other characteristics of the functioning of the PTC, we can consider them acceptable and stable in time. With respect to the number of invited people, this result is related to the number of medications evaluated (given that at least one clinician is invited per drug), which increased over the course of the study period, but above all with other activities that have increased, such as the systematic revision of the compliance of recommendations on use, protocol elaboration, and others.

The present study consists of one of the few evaluations of the activity of a pharmaceutical commission detectable in the medical literature in recent years. We believe that this can provide a starting point for defining indicators, study variables, and evaluation standards of the PTC. Indeed, this could act as a reference point for later studies, at least in Spain. In our country, Martínez López et al published a study that, although it was centred on evaluation reports, presented data on the activity of the PTC,[10] similar to ours as far as the number of medications evaluated and the rates of acceptance (somewhat higher). Weekes et al (1998) proposed a battery of indicators that they deemed useful for PTC evaluation at Australian hospitals. These 35 indicators, the majority of which were dichotomous, consisted of a qualitative evaluation that differed from the objective and methodology of the present study.[20]

Several different surveys have analysed indicators of PTC activity in distinct environments such as Belgium, England, and the USA.[21-23] In general, these have used quantitative indicators of the composition and activity of the PTC, with high variation between the scarce indicators of results.

It is possible that the principal limitation of this study is the fact that it refers to one single hospital, and as such the results are completely influenced by the dimensions, characteristics, and culture at that centre. We had to await results of a broad-scale study performed by the GENESIS group of the *Sociedad Española de Farmacia Hospitalaria* (Spanish Society of Hospital Pharmacy) that attempts to analyse the structure, function, and results of an overall PTC at the national level and whose preliminary results have been published elsewhere.[24]

Another important limitation to our study is that the evaluation was based exclusively on certain elements in the commission structure, and above all, its processes. It would be necessary in a future work to take the next step and evaluate the adequacy of decision-making given the available evidence. That is, to determine the validity of the decisions made by a commission of this type, analysing the quality of the studies that support them.

Conflict of interest

The authors affirm that they have no conflicts of interest.

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