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

SPECIAL ARTICLE
Bilingual edition English/Spanish

Drug evaluation is also a clinical activity

Evaluar medicamentos también es una actividad clínica

Eduardo López-Briz[1], Mª Dolores Fraga-Fuentes[2], Ana Clopés-Estela[3], Ana Ortega-Eslava[4], Emilio Jesús Alegre-del Rey[5]; GENESIS-SEFH Steering Committee (Appendix 1)

[1]Department of Pharmacy, La Fe University and Polytechnical Hospital, Valencia. Spain. [2]Subdirección General de Farmacia, Dirección General de Cartera Común de Servicios del Sistema Nacional de Salud y Farmacia, Ministry of Health, Madrid. Spain. [3]Pharmacy Director, Institut Català d'Oncologia, Barcelona. Spain. [4]Department of Pharmacy, University of Navarra Clinic, University of Navarra, Pamplona (Navarra). Spain. [5]Department of Pharmacy, Puerto Real University Hospital, Puerto Real (Cádiz). Spain.

Author of correspondence
Eduardo López-Briz
Avenida Fernando Abril Martorell, 106
46026 Valencia, Spain.

Email:
lopez_edubri@gva.es

Received 14 September 2020;
Accepted 22 September 2020.
DOI: 10.7399/fh.11560

How to cite this paper
López-Briz E, Fraga-Fuentes MD, Clopés-Estela A, Ortega-Eslava A, Alegre-del Rey EJ; Grupo Coordinador GENESIS-SEFH. Drug evaluation is also a clinical activity. Farm Hosp. 2021;45(1):45-7.

Abstract

The addition of a fourth year to the hospital pharmacy residency program has allowed trainees to rotate through various inpatient clinical units where they can, under the supervision of a specialist pharmacist, work shoulder to shoulder with other healthcare providers to ensure that patients receive the care they need. In addition to sharing their pharmacotherapeutic and pharmacokinetic knowledge (among others) with their colleagues, hospital pharmacists can and should contribute with their expertise in the areas of drug evaluation, selection and positioning. As no other healthcare professional masters like a pharmacist the intricacies of treatment efficacy or effectiveness, or of therapeutic safety, conveying this knowledge is yet another of the many clinical activities a hospital pharmacist must perform as a member of a multidisciplinary team, while assisting fellow-team members in deciding what medications are best suited to each patient. Both the public authorities and the pharmaceutical profession as a whole should make sure the pharmacist's role is rightfully valued and given the recognition it deserves.

Resumen

La especialidad de Farmacia Hospitalaria incorporó con el cuarto año de su programa formativo una parte importante de rotación por unidades clínicas de hospitalización en las que el farmacéutico en formación, acompañado de farmacéuticos especialistas, tiene la oportunidad de trabajar conjuntamente con otros profesionales en la atención directa al paciente. Además de contribuir a esta atención con sus conocimientos de farmacoterapia y farmacocinética, el farmacéutico de hospital puede y debe aportar al equipo su liderazgo en evaluación, selección y posicionamiento de medicamentos. Ningún profesional conoce como él los aspectos relativos a la eficacia o efectividad, seguridad y eficiencia de los tratamientos, y estos conocimientos constituyen una actividad clínica más de las que debe desempeñar en los equipos multidisciplinares, ayudando a la toma de decisiones sobre medicamentos en cada paciente. Es necesario que tanto desde los organismos públicos como desde nuestra propia profesión se ponga en valor este papel y que se potencie de forma adecuada.

KEYWORDS
Drug evaluation; Hospital pharmacy; Clinical activities; Healthcare team.

PALABRAS CLAVE
Evaluación de medicamentos; Farmacia de hospital; Actividades clínicas; Equipo de atención a la salud.

With over 40 years under its belt, the hospital pharmacy specialty enjoys excellent health and is poised at a key point in its history. According to the Royal Decree regulating the training required to become a specialist hospital pharmacist, published in 1982, the goal of the specialty is to provide the population's pharmaceutical needs through the selection, compounding, acquisition, control and dispensing of, and information about, medications; and through other activities geared toward ensuring appropriate, safe and cost-effective use of drugs and medical devices by patients and their caregivers[1]. The evolution of the specialty has since then been highly significant.

Our specialty has always been characterized by high levels of flexibility and dynamism. Our residency program, although it was introduced in 1999[2] and has since then remained unchanged despite several unsuccessful attempts for upgrading it (through no fault of the Spanish Society of Hospital Pharmacists' [SEFH]), allows us to train residents to some of the highest standards in Europe. However, the resilience of our specialty should not make us forget that the healthcare environment has undergone considerable changes in the 21 years elapsed since the introduction of our current residency program. True enough, the colleagues who designed the program back in 1999 had a strategic vision of the profession that made them add a fourth year to the program as well as a series of clinical rotations. However, although our residents nowadays perform a considerable number of clinical activities during their rotations through different inpatient units, such activities are, more often than not, carried out without adequate supervision by specialist pharmacists.

The contribution made by both specialist and resident hospital pharmacists (HPs) to the work of clinical teams and the improvements in effectiveness, safety and efficiency of pharmacotherapy achieved thanks to their involvement in patient care are beyond question[3-5]. Nevertheless, the contribution made by HPs to decisions regarding the most suitable treatment for a given patient is not always appreciated in its full relevance. The HPs knowledge and skills regarding drug evaluation and positioning in the treatment plan are essential and contribute to making the right decision in each individual case thereby achieving the goal pursued by any clinical decision, i.e. improving patients' health and quality of life. A case in point is the expertise HPs have over the evaluation of the internal and external validity of clinical trials, which is indispensable to make the right decision regarding a specific patient, with their comorbidities and personal circumstances.

Drug evaluation and selection started off in the 1970's in our country in a embrionary manner[6]. That was the time when, following in the footsteps of the pharmacy and therapeutics (P&T) committees of other European countries, the few HPs who existed back then made a decision to provide themselves of the tools required to manage the few pharmacological treatments available.

In the 50 years elapsed since then, the situation has changed radically not only in terms of the complexity of drug treatments but also because of the constant emergence of new and/or innovative treatments, in many cases still in their early development phases and therefore surrounded by significant uncertainty regarding their efficacy and safety, and often charged at unjustifiably high prices[7]. When all that was asked of a drug was that it had to be safe, efficacy and efficiency were secondary considerations which, though desirable, were not indispensable. However, the advent of highly efficient, powerful and selective drugs changed things radically, and the order of the decision-making factors was at least partly reversed, with efficacy coming to occupy the first position. After ensuring a favorable risk/benefit ratio, the next aspects to be considered should be comparative efficacy, safety, efficiency and, lastly, convenience[8].

Taking into consideration that the resources available to the National Health System for drug selection and positioning as well as for economic and budgetary assessments are scarce, it is of the essence to strengthen the System's own structures with human and economic means at different levels so that the drug selection and positioning tasks described in clinical guidelines do not fall within the purview of scientific societies. Indeed, this may lead to potential conflicts of interest and issues arising from commercial sponsorships from the industry[9].

Against this background, drug evaluation and selection as carried out by HPs should be considered key functions. In just a few years, they have gone from being a secondary, almost minority (and not very highly regarded) activity to becoming an indispensable and highly valued responsibility. Everything started at the local P&T committees. The function was then transferred to the different regions, where harmonization working groups were established. Years later, therapeutic positioning reports (IPTs) came to be issued and some scientific societies started publishing evaluation reports. One could think that HPs may have lost their evaluating role as a result of this process and that they may have gradually ceased to make their contributions to the drug evaluation and selection process. Nevertheless, HPs have never settled for treating patients with previously prescribed drugs or with medications evaluated by others. HPs have always considered drug evaluation to be part and parcel of their job, and have played an instrumental role in the advancement of this exciting activity. To perform it properly, it is not only necessary to have developed robust evidence-based critical judgement skills at the level of P&T committees, but it is also essential to be able to make informed contributions to the decision-making process that takes place within every multidisciplinary team. Indeed, HPs are in a unique position to make valuable recommendations regarding the most suitable medications to be used in each case, in terms of their efficacy/effectiveness, safety and efficiency. At present, the increasing use of medications in special situations (mainly off label medications) has become a particularly sensitive issue and a veritable challenge, which SEFH's Group for Innovation, Assessment, Standardization and Research into the Selection of Drugs (GENESIS) is currently addressing.

Fully aware of the current situation and of the social and institutional demand for and recognition of drug evaluation, both in the private and the public spheres, the GENESIS group has on numerous occasions upheld the role of HPs in this respect. The Group's strong stance stems from its belief that drug evaluation can be highly beneficial to both patients individually and to the healthcare system as a whole[10].

It is therefore necessary for HPs to actively regain their leadership as drug evaluators and restore the value of drug evaluation as a key activity in patient care, incorporating it to routine practice so that it becomes an inextricable component of clinical decision-making. Apart from their expertise as medication and pharmacotherapy experts, HPs can contribute other skills to the team such as critical appraising of the medical literature, application of evidence, and search for effectiveness, safety and efficiency, helping instill into all team members the attitude required to acquire such skills. This kind of mindset should be expressed through both the core values of our professional society and through the strategic plans of our hospital managers so that it is passed on to trainee specialists and to the whole team. The kind of literature reviews and pharmacotherapeutic sessions enabled by new IT technologies may prove very useful in this regard.

In the case of HPs, patient-centered care stems from their in-depth understanding of the drugs to be used, but not only with respect to the drugs' pharmacokinetic, pharmacodynamic or toxicity profile, but also regarding their suitability as compared with other available alternatives, the regimens whereby they are administered, the clinical relevance of patient outcomes, their incremental clinical benefit as compared with other alternatives, their economic feasibility and their positioning in the treatment algorithms. The different "subspecialty" skills of HPs, including drug evaluation and positioning, are not watertight compartments bur rather cross-cutting aptitudes that come together at the heart of the pharmacy department and are shared with the multidisciplinary team to enhance the standard of care delivered to the patient. At the same time, teamwork is required within the hospital pharmacy department itself with pharmacists working in drug evaluation and those performing clinical activities at the patients' bedside sharing knowledge and experiences and conveying them to their resident colleagues.

The recent coronavirus-induced severe acute respiratory syndrome type 2 (SARS-CoV-2) pandemic has taught us very useful lessons in this regard. Apart from activities such as procurement and logistics as well as drug distribution, formulation and compounding, all of them inherently related to the work of an HP, our participation in multidisciplinary clinical teams has consisted to a large extent in the critical assessment of a plethora of studies and clinical trials from all sorts of publications. Although some of these publications are more reliable than others, we have often been inclined to take them at their word given the scarcity of therapeutic solutions with sufficient levels of evidence[11,12]. Many of our colleagues have issued warnings in the social and the mass media against the biases contained in such publications, which has contributed to the critical appraisal of uncertainties currently prevailing in pharmacotherapeutics.

Useful —and even necessary— as social recognition may be, we also need the leaders of our profession to act decidedly to keep us focused on transforming the routines of all the hospital pharmacies in our country making sure that drug evaluation impregnates all their activities, from procurement to the monitoring of health outcomes. This requires a decisive overhaul of residency training programs to ensure that our new specialists are conversant with all the different aspects related to drug evaluation and selection and to guarantee the development of unprejudiced critical thinking (methodology, critical appraisal, clinical epidemiology), which is not often encouraged in graduate programs.

All the members of the multidisciplinary team should be fully aware that the HP is an indispensable part of the group, who has the required expertise and skills set to make recommendations to his fellow team members about the most suitable drug therapy for each patient. For our healthcare system to guarantee satisfactory health outcomes, it is essential for drug evaluation to be fully integrated into the clinical management of every patient. It is indeed essential for the system to put patients at the center in terms of drug selection, care management and decision-making at the patients' bedside. This will ensure that HPs add value to the clinical process and help improve clinical efficiency, which will no doubt benefit other clinicians and the Spanish healthcare system as a whole.

Funding

No funding.

Conflict of interest

No conflict of interests.

Appendix 1

GENESIS-SEFH Steering Committee (in alphabetical order of first surname)

Emilio J. Alegre del Rey, Vicente Arocas Casañ, Ana Clopés Estela, Laura Delgado Téllez de Cepeda, Silvia Fénix Caballero, Sandra Flores Moreno, Mª Dolores Fraga Fuentes (coordinadora), Sebastián García Sánchez, Eduardo López Briz (coordinador adjunto), Icíar Martínez López, Noemí Martínez López de Castro, Ana Ortega Eslava, Francesc Puigventós Latorre, Lucía Velasco Roces.

Bibliography

1. Real Decreto 2706/1982, de 15 de octubre, por el que se regulan los estudios de especialización y la obtención del título de Farmacéutico Especialista. Boletín Oficial del Estado, n.º 261 (30 de octubre de 1982) [accessed 06/2020]. Available at: https://www.boe.es/boe/dias/1982/10/30/pdfs/A29994-29997.pdf.
2. Ministerio de Sanidad y Consumo. Ministerio de Universidades e Investigación. Consejo Nacional de Especializaciones Farmacéuticas. Comisión Nacional de Farmacia Hospitalaria. Programa Oficial de Formación en la Especialización de Farmacia Hospitalaria. Madrid; 1999 [accessed 06/2020]. Available at: https://www.mscbs.gob.es/profesionales/formacion/docs/Farmacia_Hospitalaria.pdf
3. Dawoud DM, Smyth M, Ashe J, Strong T, Wonderling D, Hill J, *et al.* Effectiveness and cost effectiveness of pharmacist input at the ward level: a systematic review and meta-analysis. Res Social Adm Pharm. 2019;15:1212-22. DOI: 10.1016/j.sapharm.2018.10.006
4. Somers A, Spinewine A, Spriet I, Steurbaut S, Tulkens P, Hecq JD, *et al.* Development of clinical pharmacy in Belgian hospitals through pilot projects funded by the government. Acta Clin Belg. 2019;74:75-81. DOI: 10.1080/17843286.2018.1462877
5. Ma Z, Zhao Z, Sun S, Li Y, An Z, Yan Y, *et al.* Impact of 'Chief-Pharmacist System' on drug expenditures and rational drug use. Int J Clin Pharm. 2020;42:167-73. DOI: 10.1007/s11096-019-00954-9
6. López-Briz E, Fraga Fuentes D, Ortega Eslava A. Participación en comisiones: centralización o descentralización (un camino de ida y vuelta). Sociedad Española de Farmacia Hospitalaria. Monografías de Farmacia Hospitalaria y Atención Primaria. 2020 (in press).
7. Darrow JJ, Avorn J, Kesselheim AS. Approval and Regulation of Pharmaceuticals, 1983-2018. JAMA. 2020;323:164-76. DOI: 10.1001/jama.2019.20288
8. Marín R, Puigventós F, Fraga MD, Ortega A, López-Briz E, Arocas V, *et al.*; Grupo de Evaluación de Novedades y Estandarización e Investigación en Selección de Medicamentos (GENESIS) de la Sociedad Española de Farmacia Hospitalaria (SEFH). Método de Ayuda para la toma de Decisiones y la Realización de Evaluaciones de medicamentos (MADRE). Versión 4.0 [monografía en internet]. Madrid: Sociedad Española de Farmacia Hospitalaria (ed.); 2013 [accessed 06/2020]. Available at: http://gruposdetrabajo.sefh.es/genesis/genesis/basesmetodologicas/programamadre/index.html
9. No es Sano. Propuestas para asegurar el acceso a vacunas, medicamentos y material sanitario [website] [accessed 07/2020] Available at: http://noessano.org/es/wp-content/uploads/2018/10/manifiesto_noessano_web.pdf
10. Grupo GENESIS. Sociedad Española de Farmacia Hospitalaria. La Farmacia Hospitalaria ante los nuevos retos de la selección de medicamentos en España. La experiencia acumulada al servicio de toda la sociedad [monography at internet]. Madrid; 2012 [accessed 06/2020]. Available at: https://gruposdetrabajo.sefh.es/genesis/genesis/Enlaces/DOCUMENTO_MINISTERIO_21_05_2012.pdf
11. Fernández-Llamazares CM, López-Briz E. Retos del farmacéutico de hospital en la evaluación de la evidencia científica y su incorporación a los protocolos farmacoterapéuticos a través de las comisiones en tiempos de COVID-19. Farm Hosp. 2020;44(Supl 1):S24-7. DOI: 10.7399/fh.11487
12. Gil-Navarro MV, Luque-Márquez R. La farmacia hospitalaria en el equipo multidisciplinar de las unidades COVID de hospitalización. Farm Hosp. 2020;44(Supl 1):S40-2. DOI: 10.7399/fh.11517