





Original Research

Hospital Pharmacists' Intervention In Access To Innovative Therapies – Opportunities And Strategies: A Mixed-Method Design

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Abstract

Aim: Hospital Pharmacists play a crucial role in various activities within hospitals to ensure patient access to innovative therapies, particularly in the decision-making process. Their involvement spans from evaluating new therapies to ensuring compliance with legal and regulatory frameworks. However, the complexity of this process presents challenges that can delay patient access to necessary treatments. This study aims to evaluate the contribution of Hospital Pharmacists in the innovation pathway and to identify opportunities and strategies that enhance Hospital Pharmacists' intervention in improving the access to innovative therapies. By understanding these opportunities, we can develop actionable strategies to optimize the role of Hospital Pharmacists, ensuring more timely and efficient patient access to therapeutic innovations. **Methods:** A mixed-method approach was employed, beginning with semi-structured interviews to gather in-depth insights from Hospital Pharmacists. Following this qualitative phase, a survey was conducted among Portuguese Hospital Pharmacists to quantify their experiences and perceptions, receiving 58 responses. The study culminated in an expert panel discussion, comprising 12 experienced Hospital Pharmacists, to reach a consensus on strategic actions. Data collection occurred between October 2021 and March 2022. **Results:** The survey revealed that, although Hospital Pharmacists are heavily involved in supporting decision-making for the approval of innovative therapies, there are significant opportunities to optimize this process. The expert panel identified and proposed five strategic actions aimed at improving access to legal information about innovative therapies, streamlining the approval process, and fostering collaboration among stakeholders, including regulatory bodies, healthcare providers, and pharmaceutical companies. **Conclusion:** The intervention of Hospital Pharmacists in the decision-making process is critical to the access pathway for innovative therapies. Implementing the identified strategies could enhance the efficiency, speed, and effectiveness of this process, ultimately benefiting patient care by ensuring quicker access to cutting-edge treatments.

Keywords: Hospital Pharmaceutical Service, Innovative Therapies

INTRODUCTION

Over the past four decades, innovative therapies have substantially increased global life expectancy and health outcomes, with timely access to these therapies playing an essential role in attaining these results^{1,2}.

These therapies include advanced treatments such as biologics,

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CAR-T cell therapies, and orphan drugs, which present both therapeutic opportunities and regulatory challenges in hospital settings.

The inclusion of innovative therapies in hospital formulary and development of treatment protocols introduces the therapeutics into the existing clinical pathways, which is fundamental for a safe and accurate prescription process and fostering innovation in clinical practice^{3,4}. Pharmacy and Therapeutics (P&T) Committee members are the hospital staff responsible for this decision-making, assessing and managing the inclusion of innovative therapies in the hospital formulary, by evaluating the available evidence, namely safety and cost-effectiveness^{4,5}.

The decision-making process, which involves the coordination of a multidisciplinary team (physicians, pharmacists, managers, among others)⁴, is often hindered by challenges, as reported in different studies. The need for P&T Committee members to review and analyse large amounts of evidence makes it a time-consuming process, and sometimes overwhelming⁶. Additionally, the lack of standardization of the decision-making processes, shortage of human resources, P&T Committees' inadequate organization (in terms of capacity, frequency of meetings, etc.), and lack of members' specific training (e.g. economic assessment), contribute to the variability in the



access to innovation across hospitals⁶⁻⁸.

Hospital Pharmacists have a recognized intervention in Backoffice activities, including procurement, stock management, production, distribution and dispensing of therapies⁹. However, they are also increasingly involved in clinical activities, contributing to collaborative and multidisciplinary decision-making processes concerning patient treatment and managing patients' medication¹⁰.

In Portugal, Hospital Pharmacists are a crucial member of the P&T Committees, having a key intervention in the innovation access pathway. Their main responsibilities are selecting the therapies to include in the hospital formulary, ensuring formulary implementation and monitoring, developing therapeutic protocols, clinical guidelines and procedures^{11,12}.

Given the relevance of Hospital Pharmacists in the innovation access pathway, their involvement in activities that optimize this process is essential. The purpose of this study was to identify opportunities and develop strategies that leverage the intervention of Hospital Pharmacists to improve access to innovative therapies in hospitals.

Previous studies mainly describe general P&T committee functioning, while this study uniquely focuses on the strategic role of Hospital Pharmacists in the access pathway to innovative therapies in Portugal. This focus, combined with practical recommendations on how these professionals can better intervene in Access to innovative therapies, makes it a novel contribution to the field.

METHODS

Study design

An exploratory sequential mixed-methods design, developed in two phases. First, we identified, through a survey, Hospital Pharmacists' key activities and main bottlenecks in the hospitals' access pathway to innovation, and then conducted an expert panel to reach a consensus regarding improvement opportunities and developed a strategic action plan for implementation.

Data collection

A self-reported and anonymous quantitative survey, targeting Hospital Pharmacists, was implemented between October 2021 and March 2022. The survey was developed based on a literature review focusing on the challenges other countries face in the access to innovative therapies, and semi-structured individual interviews with Portuguese Hospital Pharmacists (n=9) regarding their perspectives, experiences, and interventions in this pathway. The survey included questions about the hospital's current access pathway to innovation and level of knowledge and access to legislation on the topic. The Hospital Pharmacists' intervention in each activity was assessed (yes/no) as well as level of importance (high/low). The survey was validated by 3 Hospital Pharmacists members of the SPFCS - Portuguese Society of Healthcare Pharmacists and shared with SPFCS members. All participants were informed about the

study and provided their willingness and consent to participate.

Reaching a consensus

Based on the results from the survey, a focus group was conducted with Hospital Pharmacists experts (n=12) from 11 Portuguese hospitals in October 2022. Purposive sampling techniques were applied to recruit Hospital Pharmacists from various hospitals across Portuguese territory. Members of the SPFCS made face-to-face contact with the Hospital Pharmacists to inform them about the date and time of the focus group after explaining to them the purpose of the study and obtaining their willingness and consent to participate. The focus group was facilitated by a member of the research team. The group was encouraged to discuss the bottlenecks previously identified, ranking them from highest priority to be addressed to lowest priority (1 to 5). Subsequently, improvement opportunities were discussed in small groups, and action plans were developed, including actions to implement, stakeholders to involve, and metrics to monitor success. During the focus group, team member took field notes. The data were analysed to draw conclusions using inductive thematic content analysis, and the results were subsequently shared and validated by the participants.

RESULTS

Quantitative survey

A total of 58 Hospital Pharmacists (24.1% were Pharmacy Directors, n=14) from 31 Portuguese hospitals answered the survey. The results demonstrated that Hospital Pharmacists are involved in the main steps of access to innovation in hospitals, although the degree of participation varies significantly across institutions.

The most important activities identified were related to Hospital Pharmacists' support in the decision-making process, including interpretation of the applicable legislation on the access to innovative therapies, assessment of therapies for inclusion in hospital formulary (economic impact, effectiveness, and safety) and development of hospital clinical protocols. These activities require strong alignment and collaboration between prescribers and other members of the P&T Committee. However, the survey also uncovered bottlenecks, namely disparities in the Hospital Pharmacists involvement in these activities across different hospitals.

62.1% (n=36) of Hospital Pharmacists considered that the legislation on access to innovative therapies is unclear, scattered, and difficult to interpret. 56.9% (n=33) reported insufficient knowledge among health professionals to interpret this legal information, and 50.0% (n=29) reported lack of support from Health Authorities at national level to address this knowledge gap. Consequently, Hospital Pharmacists reported inconsistent decision-making practices related to new therapies (56.9%, n=33), and increased administrative burden (51.7%, n=30), such as excessive time and effort trying to navigate through complex legislation.

50.0% (n=29) reported no participation in scientific assessment



of innovative therapies that support the P&T Committee's decision-making, and 46.6% (n=27) are not involved in the economic impact analysis, despite these activities being considered highly important for the access pathway to innovation. Additionally, only 39.7% (n=23) of Hospital Pharmacists stated being involved in multidisciplinary treatment decision meetings.

Consensus - Opportunities and Strategies

It was consensual that the main opportunities to improve the access to innovative therapies in hospitals are on optimizing the decision-making process. The expert panel identified 3 main opportunities and developed 5 strategic actions involving Hospital Pharmacists, as described below and presented in Table 1.

Table 1. Strategic action plan developed by the experts panel, including opportunity areas, strategic actions and their objectives and the plan to achieve them

AREA	STRATEGIC ACTIONS AND OBJECTIVES	ACTION PLAN
Legislation on access to innovative therapies	ACTION 1: Centralize access to applicable legislation	<ul style="list-style-type: none"> Creation of an expert pharmacist working group to review and summarize the legislation applicable to access to innovative therapies.
	Objective: Reduce time invested in searching for legislation applicable to access to innovative therapies.	<ul style="list-style-type: none"> Development of a dynamic, accessible, and constantly updated digital platform, which aggregates legislation and information of interest, aimed at Hospital Pharmacists, but also available to all healthcare professionals.
Legislation on access to	ACTION 2: Training Hospital Pharmacists on relevant legislation interpretation	<ul style="list-style-type: none"> Development and implementation of a training plan, targeting hospital pharmacists, on legislation applicable to innovative therapies' access (pre- and post-Marketing Authorization) and their applicability to hospital practice decisions:
	Objective: Decrease different interpretation of legal framework concerning access to innovative therapies among professionals.	a. Short explanatory videos
		b. Frequently asked questions sheet
		c. Q&A forum shared by pharmacists from different institutions
Hospital approval process of access to innovative therapies	ACTION 3: Promote Hospital Pharmacists' intervention in multidisciplinary treatment decision-making	<ul style="list-style-type: none"> Generate evidence on Hospital Pharmacists' added value to therapies decision-making regarding access to innovative therapies:
	Objective: Enhance a more informed clinical decision, as well as an optimal approval of inclusion of innovative therapies and development of hospital protocols.	a. Evaluation of patient outcomes (Hospital Pharmacists' intervention vs non-intervention)
		b. Engaging testimonials from other health professionals (such as physicians) highlighting the importance of Hospital Pharmacists' intervention in innovative therapies access process.
		<ul style="list-style-type: none"> Development of a recommendation proposal, in partnership with pharmacy faculties, to support training and integration of Hospital Pharmacists in decision-making appointments, sharing responsibilities with physicians.
Hospital approval process of access to innovative therapies	ACTION 4: Support and regulate Pharmacy and Therapeutics Committee's activity	<ul style="list-style-type: none"> Development national guidelines to support Pharmacy and Therapeutics Committee's activity, detailing the intervention and responsibilities of each member, guides for preparing agendas and meeting the minutes, among others;
	Objective: Ensure the alignment of Pharmacy and Therapeutics Committee decisions among the different institutions, as well as optimized approval of hospital protocols.	<ul style="list-style-type: none"> Involvement of inspection entities to supervise the activity of Pharmacy and Therapeutics Committee across hospitals.
Stakeholders' collaboration	ACTION 5: Improve communication between health professionals	<ul style="list-style-type: none"> Map the activities throughout the access pathway of innovative therapies at hospital level;
	Objective: Make the access pathway more efficient and minimize entropies.	<ul style="list-style-type: none"> Identify the main communication channels to implement a feedback system at each pathway stage, supervising all the process.

Improving access to clear legal information about innovative therapies

To ensure timely access to innovative therapies in hospitals, it is recommended to optimize access to clear legal information, by creating a training plan targeting Hospital Pharmacists, focusing on legislation on access to therapies (pre- and post-Marketing Authorization) and its applicability to hospital practice decisions. Additionally, it is essential to support Hospital Pharmacists with tools and knowledge to interpret this information and help

other healthcare professionals in the decision-making process - this could be done via the development of an up-to-date digital platform with consolidated legal information, that should be accessible to all healthcare professionals.

Standardizing the approval process of innovative therapies

To enable a more informed and faster clinical decision, it is essential to promote a broader intervention of Hospital Pharmacists in the development and approval of hospital



protocols. Additionally, it is important to support, regulate and develop guidelines for the P&T Committee's activity, ensuring the standardization of processes across hospitals, compliance with approval times, among others.

Moreover, to promote an efficient sharing of responsibilities between pharmacists and other health professionals, it is important to define good practices/recommendations regarding the Hospital Pharmacists' intervention.

Strengthening collaboration among all stakeholders

It is essential to promote collaboration to ensure that the decision-making process for the access to innovative therapies is based on the knowledge of a group of a diverse healthcare team with different expertise.

Actions aimed at strengthening collaboration among physicians and pharmacists involved in the decision-making process, were deemed priority. They include mapping all the activities to identifying the main communication channels along the pathway and implementing a feedback system at each stage of the process.

DISCUSSION

Our study highlights the main opportunities to improve the access pathway to innovative therapies within hospitals, which lie in the therapeutic decision-making process. Consequently, the improvement strategies developed are focused on the intervention of Hospital Pharmacists in this process. Its implementation aims to make the therapy decision-making process faster and the process of accessing innovative therapies more informative and efficient.

The expert panel agreed that it is essential to improve Hospital Pharmacists' access to applicable legislation, which reduces time spent searching for information and avoids misinterpretations by different healthcare professionals.

Aligned with opportunities previously identified in other studies^{3-5,13}, we concluded that it is essential to better organize and structure the therapy decision-making process. Thus, we propose measures aimed at increasing the involvement of trained Hospital Pharmacists in the multidisciplinary treatment decision and alignment and coordination of the P&T Committee therapies' approval process, making the process organized and transparent.

Finally, from a cross-sectional perspective, all panel members identified that strengthening collaboration between healthcare professionals at each stage of the access to innovative therapies pathway is key to improve the process, as other authors have previously concluded^{3,13,14}.

The devised action plan holds the potential to assist other hospitals in implementing strategies aimed at enhancing the access pathway to innovative therapies.

Despite these valuable insights, this study has limitations, particularly the reduced number of participants in the survey, compared to the total number of 923 active Hospital Pharmacists in Portugal¹⁵. Future research would benefit from increasing the number of expert panels, encompassing other healthcare professionals involved in the access pathway to innovative therapies.

These findings align with global health priorities such as the World Health Organization's roadmap for equitable access to medicines and the objectives of Universal Health Coverage, by reinforcing the role of pharmacists in ensuring timely, evidence-based access to essential and innovative therapies, including advanced treatments such as biologics or CAR-T cells¹⁶. Enhancing hospital-level processes contributes to broader healthcare system resilience and patient-centred care.

CONCLUSIONS

In conclusion, our study identifies significant opportunities to enhance the access pathway to innovative therapies within hospitals, particularly by improving the therapeutic decision-making process. The involvement of healthcare professionals in multidisciplinary decision-making, along with improved alignment and transparency in the P&T Committee's approval process, can contribute to more organized and efficient access to innovative treatments.

Additionally, improving Hospital Pharmacists' access to relevant legislation is essential to streamline the process and avoid misinterpretations. Strengthening collaboration among healthcare professionals at every stage of the access pathway will further enhance the process, ensuring that innovative therapies reach patients more effectively.

The proposed action plan provides a roadmap for other hospitals to implement strategies aimed at optimizing access to innovative therapies. However, further studies are required to validate these findings, involving a larger and more diverse group of healthcare professionals.

CONFLICTS OF INTEREST

Susana Santos is an employee of Janssen-Cilag. Margarida Ferro and Joana Sousa are employees of MOAI Consulting, the company that was paid for the medical writing of this manuscript. The other authors declare that there are no conflicts of interest.

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