

Hospital Pharmacists' Intervention in Access to Therapeutic Innovation in Portuguese Hospitals

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INTRODUCTION

Hospital Pharmacists' (HP) intervene in critical medicines activities in hospitals, including procurement, stock management, production, distribution and dispensing.¹ Also, increasingly contribute to collaborative and multidisciplinary decision-making processes, ensuring the patients' access to therapeutic innovation.² In Portugal they have an important responsibility in selecting the therapies to be included in the hospital formulary, through the Pharmacy and Therapeutics (P&T) Committee, contributing to the development of treatment protocols, clinical guidelines and procedures³, but sometimes this intervention goes unnoticed. Given their relevance, it is crucial to better understand the HP' intervention in the hospital access pathway to therapeutic innovation.

OBJECTIVE

This study aimed to characterize the intervention of HP on the access pathway of innovative therapies by mapping and quantifying activities within the hospital, while identifying improvement opportunities.

METHODS

- Data collection was performed through an exploratory sequential mixed-methods design. Qualitative data was collected through semi-structured interviews with HP (n=9) to map the activities in the access pathway of innovative therapies, their perspectives and experiences.
- A subsequent anonymous online quantitative survey was implemented to assess the intervention of HP in each activity of the pathway, from development and approval of hospital protocols to therapy acquisition and dispensing.
- The intervention was assessed through analysis of participation (yes/ no), time spent (average time spent per activity) and level of importance of each activity (numeric rating scale of 1 – *not important* to 5 – *critical*).

RESULTS

Between October 2021 and March 2022, a total of **49 HP** (11 Pharmacy Directors and 38 Pharmacists) from **27 Portuguese Hospitals** answered the questionnaire. The geographical distribution of participants covered all 5 Portuguese main areas (North, Center, Lisbon and Tagus Valley, South and Islands).

1. Characterization of HP' intervention on access pathway of innovative therapies

1.1 Overview

The results demonstrated a monthly average of **4 new innovative therapies** per institution, but the HP' intervention in the access pathway to these therapies depends on the approval status by the local or central regulatory health authority.

The number of HP involved in access to therapies with a marketing authorization and reimbursement decision was lower than in access to therapies without marketing authorization and while awaiting a reimbursement decision by the local health authority (Figure 1).

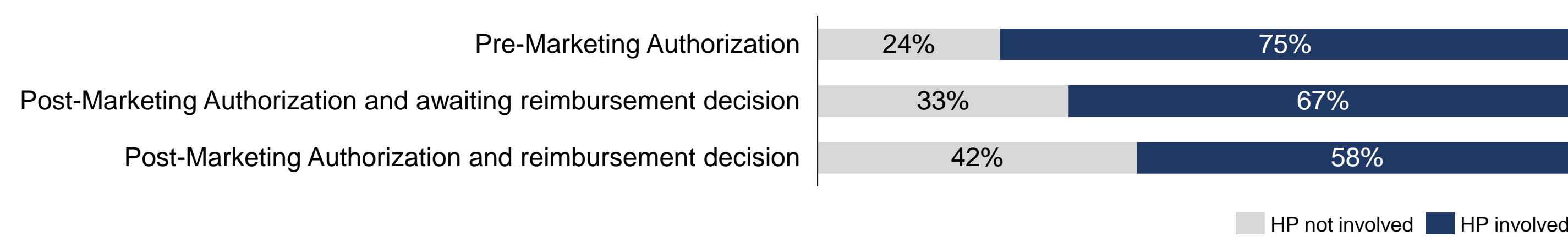


Figure 1 – HP' involvement in the access pathway of innovative therapies according to the therapy approval status.

1.2 Hospital access pathway

Along the hospital access pathway of innovative therapies, HP reported being involved in all main stages, from therapeutic approval decision-making to therapeutic acquisition and dispensing, collaborating with different stakeholders. Figure 2 summarizes **the hospital access pathway**, detailing the **stakeholders involved** and the **participation of HP**.

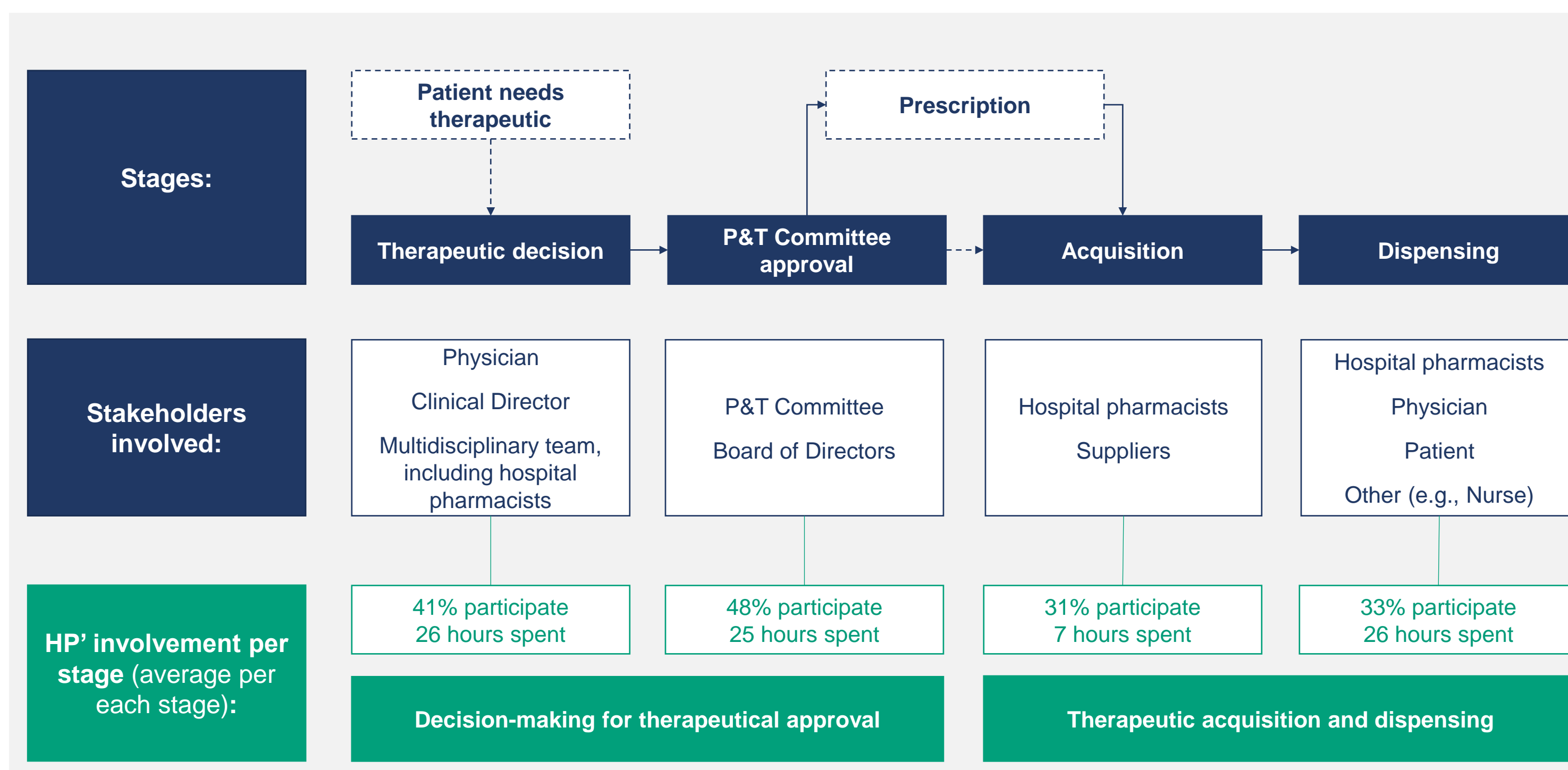


Figure 2 – Diagram of the hospital access pathway

1.2.1 Decision-making for therapeutic approval

HP's intervention in the decision-making process for therapeutic approval was characterized by a set of sequential activities, related mainly to supporting the prescription decision and the P&T Committee decision, including the approval and development of hospital protocols.

Support the therapeutic prescription decision:

The activities at this stage are mainly related to the analysis and interpretation of legislation to support prescription decision-making. HP classified their role in legislation analysis as crucial for decision-making, and agreed all that pharmacists are the healthcare professionals best prepared to understand this legislation.

On the other hand, the involvement of HP in multidisciplinary meetings for therapeutic decisions was classified as important for the access pathway and as one of the most time-consuming activities. However, 65% stated they are not a part of these meetings, of which 43% indicated the lack of human resources as the main reason for this.

Support the P&T Committee decision:

As members of the P&T Committee, HP reported to play a crucial role in activities related to decision-making about innovative therapies (Figure 3), leading to the approval and development of treatment protocols and their inclusion in the hospital formulary.

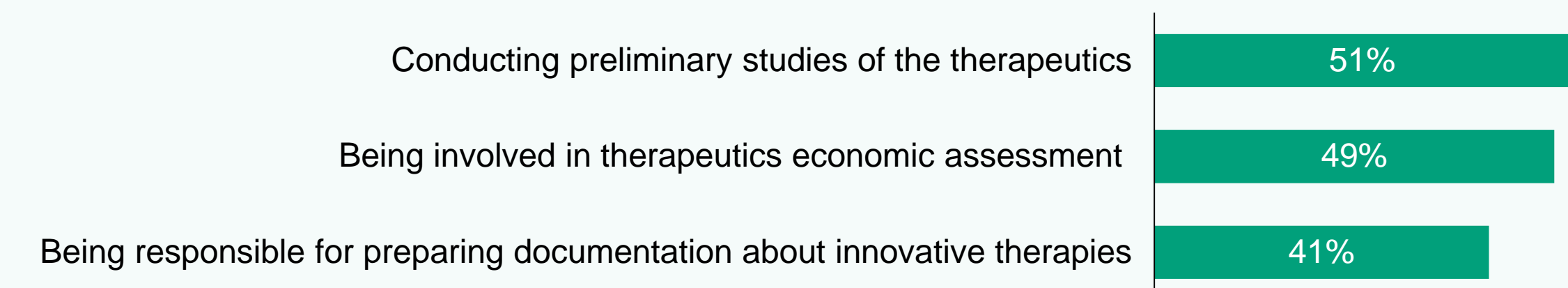


Figure 3 – HP's intervention in the P&T Committee's decision-making support.

1.2.2 Therapeutic acquisition and dispensing

HP's intervention in therapeutic acquisition and dispensing encompasses a set of back-office activities to ensure the patients' timely access to innovative therapies. 24% of HP reported being involved in the opening of public tender, 20% support negotiations with the supplier and 39% participate in the reception of therapies – these activities were classified as of low importance. Regarding dispensing, 45% of HP reported being involved in the treatment preparation.

2. Improvement opportunities

Throughout the mapping of HP' intervention in the access pathway to innovative therapies, opportunities for improvement were identified, as summarized in Table 1.

Areas	Improvement opportunities identified
Therapeutic legislation	<ul style="list-style-type: none"> 63% of HP reported that information regarding legislation is unclear, scattered, and difficult to interpret, which increases the administrative burden, time and effort needed. 33% reported insufficient knowledge among health professionals to interpret this legal information and 27% identified a lack of support from National Health Authorities to address this gap. 26% identified delays in access to innovative therapies due to lack of access to legal information.
Therapeutic approval process	<ul style="list-style-type: none"> 28% identified inconsistent decision-making practices, especially due to the lack of standardization of the P&T Committee activities across hospitals.
Collaboration and communication along the access pathway	<ul style="list-style-type: none"> 57% reported a lack of recognition of the role of HP by other professionals, resulting in disparities of HP' involvement in the multidisciplinary treatment decision meetings.

Table 1 – Improvement opportunities identified.

CONCLUSION

HP are involved in all stages of the access pathway to therapeutic innovation within hospitals, with a critical role in the decision-making stages for the introduction of therapies into the hospital formulary. Throughout the mapping process, opportunities for improvement were identified, particularly, in areas related to legislation, the approval process by the P&T Committee and communication among the other stakeholders involved.

LIMITATIONS

The questionnaire involved a limited number of participants compared to the total number of 923 active HP in Portugal⁴. It would be beneficial to extend the study to include a greater number of responses to make the analysis more robust.