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

PROTOCOL
Bilingual edition English/Spanish

# Assessing patient experience with a Telepharmacy model coordinated in the hospital and rural pharmacy setting: The TELEMACO project

# Evaluación de la experiencia del paciente con un modelo de atención farmacéutica telemática coordinada entre farmacia hospitalaria y farmacia rural. Proyecto TELÉMACO

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## Abstract

**Objective:** To determine variation in patient experience with a model of Telepharmacy coordinated in the specialist hospital and rural pharmacy setting.

**Method:** A pre-post experimental analytical study. A set of common essential pharmacy tasks based on the capacity-motivation-opportunity method will be performed in each participating site.

A a Telepharmacy software will be designed to include the following functionalities: history of patient pharmaceutical profiling and prioritization; scheduled appointment book; unscheduled visit record; generic participant communication wall; patient-professional instantaneous messaging chat; video calls; monitoring of treatment adherence; and evaluation of patient-reported outcomes.

Inclusion criteria: age older than 18 years; being on regular hospital pharmacy follow-up for the last 6 months; using a stable drug therapy (without treatment changes in the last 6 months); using a chronic hospital outpatient prescription (any prescription valid for at least 6 months); living in any of the municipalities served by the participating pharmacies or using the services of a participating pharmacy located near the usual place of residence; granting informed consent prior to inclusion in the study. A 48-week follow-up will be performed of each patient.

## KEYWORDS
Telepharmacy; Telemedicine; Pharmaceutical care; Hospital pharmacy; Rural pharmacy.

## Resumen

**Objetivo:** Determinar la variación en la experiencia del paciente con un modelo de atención farmacéutica coordinada entre farmacia hospitalaria y farmacia rural especializado y el rural de atención comunitaria, basado en la incorporación de la Telefarmacia.

**Método:** Estudio analítico experimental de intervención antes-después. Para desarrollar el proyecto se realizarán una serie de procedimientos comunes e indispensables, basados en la metodología capacidad-motivación-oportunidad, en cada uno de los centros.

Se diseñará una aplicacion informática de Telefarmacia que contemplará, entre otras, las siguientes funcionalidades: historial de caracterización y priorización farmacoterapéutica de los pacientes; agenda de visitas programadas y registro de visitas no programadas; muro de comunicación genérica entre participantes; chat de mensajería instantánea entre pacientes y profesionales; videollamadas; monitorización de la adherencia a la medicación y valoración de cuestionarios de resultados reportados por pacientes.

Se incluirán: pacientes mayores de 18 años; en seguimiento habitual en consultas externas de farmacia hospitalaria durante más de 6 meses previo al inicio del estudio; que se encuentren en situación estable desde el punto de vista farmacoterapéutico (sin cambios de tratamientos en los últimos 6 meses); que tengan prescrito, al menos, un tratamiento crónico de dispensación en oficina

## PALABRAS CLAVE
Telefarmacia; Telemedicina; Atención farmacéutica; Farmacia hospitalaria; Farmacia rural.

The primary endpoint will be variation in patient experience, as assessed using the *"Instrumento de Evaluación de la eXperiencia del PAciente Crónico"* scale at baseline and at the end of the follow-up period.

**Conclusions:** The incorporation, development and implementation of a coordinated Telepharmacy care model will help us determine whether this model is useful in improving patient follow-up and communication with pharmacy professionals at different levels of healthcare.

de farmacia (prescripción con una vigencia de más de 6 meses de cualquier fármaco); que residan habitualmente en las localidades de las oficinas de farmacia participantes en el estudio o que acudan a las mismas por cercanía a su lugar de residencia habitual; y que otorguen su consentimiento informado de participación. Cada paciente tendrá un seguimiento de 48 semanas.

La variable principal será la diferencia en la experiencia del paciente, valorada mediante la escala "Instrumento de Evaluación de la eXperiencia del PAciente Crónico", desde el inicio hasta el final de seguimiento.

**Conclusiones:** La puesta en marcha, desarrollo e implementación de la metodología de atención farmacéutica coordinada, basada en la Telefarmacia, permitirá identificar, a partir de su medición, si esta metodología consigue llevar a cabo un seguimiento más oportuno de los pacientes incluidos, y si proporciona una mejor experiencia de los mismos en su relación con los profesionales farmacéuticos que les atienden en los diferentes niveles de atención sanitaria.

## Introduction

In the recent years, the health system, society, and the profile of patients using outpatient hospital pharmacy (HP) services have changed substantially, resulting in HPs having gained relevance in the field of financial and healthcare strategies. Therefore, it is essential that the needs of HPs are met and health outcomes are assessed to ensure the sustainability of the system[1,2].

In 2015, the Spanish Society of Hospital Pharmacy (SEFH) launched the *"Strategic outpatient care plan, MAPEX)"*[3] to open a new line of action aimed at improving outpatient hospital pharmacy care and reinforce HP leadership in drug therapy management and healthcare coordination. After an initial survey performed in 2016 to assess the current situation and following the first consensus conference, the SEFH started to develop the strategic lines of work of the MAPEX project. This included a re-definition of the concept of Pharmaceutical Care (TPC); integration of PHs in multidisciplinary teams; development of stratification models; and the incorporation of new drug therapy monitoring technologies, to name a few. Later, the "CMO pharmaceutical care model" was developed based on the priority pillars identified in current patients: capacity (using stratification models for individualized HP care); motivation (administering target-oriented drug therapies using motivational interviews); and opportunity (developing a continuous technology-based HP care model) to improve health outcomes[4].

In 2019, a Consensus Document was presented, where a new definition of PC was proposed. Core HP activities included multidisciplinary inter-level coordination; stratified care; homogeneity of interventions; continuous technology-based communication; and improvement of patient experience[5].

Although long-term use of a drug therapy is challenging for all patients, patients living in rural areas face added difficulties, due to the particularities of their environment. It is the case of patients living in small isolated villages far away from big cities and hospitals of reference, due to geographical distance and lack of communications[6,7].

The outbreak of the COVID-19 pandemic forced all hospitals in Spain to immediately incorporate Telepharmacy services to their portfolio of services, with impressive results reported by hospital pharmacy professionals in terms of logistics and medication delivery[8,9]. The SEFH recently published a Positioning Statement and a *Strategic Plan for the Expansion and Development of Telepharmacy,* where the Society identified four primary scopes of application that needed to be reinforced: drug therapy monitoring; patient education and training; healthcare team coordination; and dispensation and informed delivery of medication[10].

In the light of the aforementioned, a research study was necessary to gather solid scientific evidence on the usefulness of Telepharmacy, where emphasis is placed on pharmaceutical care procedures and use of technologies assessed from patient's perspective and experience.

### Hypothesis and objectives

A model of telepharmaceutical care (TPC) coordinated in the hospital pharmacy and rural pharmacy setting will improve patient experience with hospital prescriptions, as compared to the conventional model.

*Primary objective*

To determine whether a model of telepharmaceutical care coordinated in the hospital pharmacy and rural pharmacy setting improves patient experience with hospital prescriptions, as compared to the conventional model.

*Secondary objectives*

- To describe and characterize the global cohort of subjects included in the study in terms of the variables identified as relevant in this protocol.
- To describe and characterize the number and type of scheduled and unscheduled interventions performed, either in-person or virtual, based on the taxonomy model available for this TPC model.
- To determine whether the TPC model under study improves the quality of life and satisfaction of patients, with respect to the baseline situation.
- To determine whether the TPC model improves treatment adherence and health outcomes, with respect to the baseline situation.
- To determine the level of satisfaction of health professionals with the TPC model.
- To determine the influence of the patient-reported data collected through questionnaires.

## Methods

### Study design, scope and term

This study was designed as an analytical pre-post experimental interventional study. All the tasks established in this protocol are frequent in routine practice, except for drug therapy monitoring by the HP.

All participating professionals will receive training in the new patient follow-up methods and use of the Telepharmacy platform. In addition, a technical assistance service will be available to help solve technical issues.

The study will be carried out in five HP services and 29 rural community pharmacies located in the same provinces as the respective participating hospitals. 'Rural community pharmacy' (RP) is defined by the Spanish Society of Rural Pharmacy (SEFAR) as *"community pharmacies located in towns or villages in rural areas, with 'rural area' being defined as all municipalities which economy is mostly based on livestock and agriculture and have one or two community pharmacies"*[7], and the definition of rural area provided in Spanish Law 45/2007 of December 13 for the sustainable development of rural areas[11]. Urban or periurban community pharmacies are excluded from the study.

The study will be performed between March 2021 and March 2023.

### Study population

*Inclusion and exclusion criteria*

Inclusion criteria. All patients must a) have an age > 18 years; b) have been on regular outpatient follow-up by the hospital pharmacy for at least 6 months prior to initiation of the study; c) receive a stable treatment (without treatment changes in the last 6 months); c) have a chronic hospital prescription (any prescription valid for at least 6 months); d) live in any

of the municipalities served by the participating pharmacies or using the services of the participating pharmacies because they are near the usual place of residence; e) provide informed consent to participating in the study.

Exclusion criteria: inability to complete the study questionnaires; and lacking autonomy to use the Telepharmacy platform available for follow-up.

All evaluations and results that confirm compliance with inclusion criteria and not meeting any exclusion criteria will be recorded in the medical history of the patient. Failure to m*eet al.*l inclusion criteria or meeting one or several exclusion criteria is considered a selection failure.

*Inclusion and allocation of a patient ID code*

Subjects complying with all inclusion criteria and not meeting any exclusion criteria will be included in the study and will be assigned an anonymous ID code to preserve their identity.

*Sample size*

It is estimated that one in three patients living in rural areas (33%) does not obtain high scores on the *"Chronic patient experience assessment platform"* (IEXPAC). Assuming an alpha error of 5% and a power of 80%, a sample of 72 patients will be needed to demonstrate that the use of the coordinated TPC model improves patient experience, as assessed on the IEXPAC scale. Assuming a percentage of drop-outs of 10%, 80 patients will be needed.

## Study procedures

A set of essential tasks that are common in routine practice will be performed for the purposes of the study (Table 1).

*Baseline visit*

Candidate patients will be recruited sequentially by the HP. Competitive patient recruitment will not be performed. The study team will ensure that each patient meets all inclusion criteria and no exclusion criteria. In such a case, the purposes of the study will be thoroughly explained to the patient. Prior informed consent will be required for participation in the study.

Patients will be stratified (in case they have not already been stratified) based on the model applicable to each of the conditions managed in outpatient care. PH interventions will be tailored to each individual case[12]. Patients will be trained in the use of the Telepharmacy platform. A manual of use will be distributed among the study patients.

To assess quality of life, treatment adherence, and satisfaction with the TPC model, all patients will be asked to complete a battery of questionnaires at baseline.

*Follow-up visits*

Face-to-face and virtual appointments will be scheduled for the following 6 months. These appointments can also be scheduled to coincide with the next in-person hospital appointment within the next 6 months. Medication will be dispensed for a maximum of 3 months. The study team will determine the amount of medication to be delivered in each dispensation, according to the individual follow-up plan established for each patient.

When dispensation is not performed during the in-person hospital visit, the HP and the rural pharmacy will coordinate the delivery of hospital prescriptions at the rural pharmacy. Otherwise, an alternative pathway will be established (home delivery or delivery at the closest healthcare center). Once the patient has received their medicines, he or she will attend a face-

**Table 1.** Diagram of study procedures and scope of application

| Scope of application | Procedure | Selection | W 1-4 | W 12 | W 24 | W 36 | W 48 |
|---|---|---|---|---|---|---|---|
| | | Baseline visit | | | | | Final visit |
| HOSPITAL | Informed consent and initial documentation | X | | | | | |
| HOSPITAL | Patient stratification | X | | | | | |
| RURAL | General and specific PRO monitoring | | | X | X | X | X |
| HOSPITAL + RURAL | Scheduled monitoring teleconsultations* | | | X | X | X | **X** |
| HOSPITAL + RURAL | Unscheduled monitoring teleconsultations** | | | | | | |
| HOSPITAL | Shipping of medication*** | | X | X | X | X | |
| HOSPITAL + RURAL | Traceability of medication shipping and reception | | X | X | X | X | |
| HOSPITAL + RURAL | Preestablished interventions by patient priorities**** | X | X | X | X | X | X |
| HOSPITAL | IEXPAC | X | | | | | X |
| HOSPITAL + RURAL | Assessment of baseline and final adherence | X | | | | | X |
| HOSPITAL + RURAL | Patient satisfaction with hospital and rural community pharmacy | X | | | | | X |
| HOSPITAL + RURAL | Healthcare professional satisfaction with the platform | | | | | | **X** |

Final IEXPAC: Chronic patient experience assessment tool (11+4 telephonic) and satisfaction questionnaires at week 48 will be completed by a member of the external professional team other than the study team.

PRO: patient-reported outcome; W: week.

*They will be performed using the Telepharmacy platform available for patients. **It will be performed at any time based on the needs of the patient or study team. ***According to the pathway established. According to the jointly established plan. ****Performed jointly by the study team in the field of hospital pharmacy and rural community pharmacy.

to-face appointment at the RP for drug therapy monitoring to be performed within 48h.

Scheduled and unscheduled virtual consultations will be carried out with the participating RPs.

The RP and HP professionals involved in the study will schedule as many virtual appointments as they deem it necessary for the correct follow-up of patients.

Every in-person/virtual consultation at any level of healthcare will include a CMO-based motivational interview.

#### *Final visit*

Participation in the study will end when the patient has completed a follow-up period of 48 weeks. Patient completion of the follow-up period will be immediately reported, for the External Committee to perform the final assessment using the IEXPAC questionnaire. IEXPAC version 11+4 adapted to telephone calls will be used. The same version will be employed at the baseline visit[13,14].

Patient follow-up will continue as established by the participating hospital of reference. The patients who, for whatever reason, withdraw from the study will also be registered in the Telepharmacy platform. The reason of withdrawal (drop-out, clinical cause, hospitalization, exitus or other) will be recorded. Drop-outs or patients who withdraw from the study will not be replaced with other patients.

## Telepharmacy platform

A computer application will be designed to include the following functionalities:

- History of drug therapy profile and prioritization.
- Scheduled appointment book and unscheduled visit record.
- Generic communication wall for participants.
- Patient-professional instantaneous messaging chat.
- Video calls.
- Treatment adherence monitoring and patient-reported outcome assessment.

## Goal compliance variables

Patient experience will be assessed using the IEXPAC scale. This scale assesses patient experience and course. Patient experience is defined as patient-reported encounters and events that occur across the continuum of care provided by healthcare and social professionals and services, and patient perception of such encounters and their results. To avoid bias, the questionnaire will be administered by research support technical professionals other than the study team of each of the participating site. Assessments on the IEXPAC5 scale will be carried out at baseline and at the end of the study.

#### *Secondary endpoints*

Number and type of in-person and virtual interventions performed by the coordinated study group. Three levels of priority will be established according to SEFH's stratification models. The actions to be developed in each scope of application will be included (drug therapy monitoring, patient education and training, healthcare team coordination).

#### *Variables for measuring secondary endpoints*

Number of visits and unscheduled contacts with the pharmacy service. Number of drop-outs. Number of hospital admissions during the study. Patient satisfaction. Professional satisfaction with the platform and the pathway established.

Proportion of patients with good adherence to hospital or concomitant treatment > 90% at week 48, as assessed by the Morisky questionnaire and by dispensation records (at the HP and at the community pharmacy). Good treatment adherence is defined as compliance with *all* prescriptions, as assessed by the two methods.

Patient-reported outcome (PRO) questionnaires will be used in the study, including the *General SF-12* and *EUROQoL-5D* questionnaire[15]. The study team will ask permission from the authors before using these questionnaires. All PRO questionnaires, available on the Telepharmacy platform, will be completed by the patients at least once every three months. A comparative study of baseline and final scores and final score quartile distribution will be performed[16].

## Data collection

Each participant will be asked to complete a Case Report Form (eCRF) complying with integrity, accuracy, reliability and consistency requirements.

All data recorded on the eCRF should be directly extracted from the medical history or from source documents such as laboratory or imaging study reports. ECRF data must be consistent with source document data; otherwise, discrepancies will require justification. It is the responsibility of the investigator to review all eCRFs, ensure that they are correctly completed, and approve and sign them.

## Statistical analysis

Upon study completion, a statistical analysis will be carried out. All statistical tests used for data analysis will be detailed in the Statistical Analysis Plan. All deviations from the original Statistical Analysis Plan will be recorded and justified on the final report of results.

#### *Analysis population*

The intended-to-treat population will consist of all patients included in the study, regardless of them having completed or not the follow-up period.

#### *Imputation of missing data*

Only complete cases will be included for analysis. Imputation of missing data will not be performed. The volume of missing data will be reported in each description of results.

## Ethical considerations

This study was approved by the Institutional Review Board of Research on Medicinal Products Sur of Seville.

# Discussion

The outbreak of the COVID-19 pandemic in Spain in March 2020 forced the establishment of new pathways for the delivery of medication to ensure the continuity of outpatient hospital pharmacy care. Telepharmacy programs were focused on logistics, and were considered satisfactory both, by patients and by healthcare professionals.

More recently, the ENOPEX study undertaken by the SEFH demonstrated the need for new pharmaceutical care pathways and platforms for the coordination of drug therapy monitoring. According to the study, these pathways should be less focused on the delivery of medication and more centered on professional-patient interaction and shared decision-making between patients and healthcare professionals[17].

A strength of this project is that the study team was composed of professionals with experience in the application of the TPC model tested, and in the conception, design, and implementation of Telepharmacy platforms such as that employed in this study. Another strong point is that the different procedure stages and interventions were thoroughly reviewed. This added to the multicentric design of the study warrant the future application of the platform in other centers.

A limitation of this study is that the platform is not integrated in the information systems and electronic medical records of the participating centers, which will require that clinical data are recorded on the two systems. In addition, in some centers, the use of the specific TPC model of the study was not generalized, which will make it necessary that new workflows and pathways are established in these centers other than the ones routinely used by the participating professionals.

This model will bring a revolution in the field of hospital and community pharmacy care, especially in rural areas. Thus, our TPC model will help

identify the patients who will benefit the most from specific pharmaceutical interventions, which will ultimately result in improved health outcomes. This way, interventions will be tailored to the individual patient profile.

Finally, the results of this study will presumably provide evidence that the incorporation of new technologies improve coordination of pharmaceutical follow-up of patients.

## Funding

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## Conflict of interests

No conflict of interests.

## Contribution to the scientific literature

This study will help determine the influence and advantages of this technology-based model of coordinated Telepharmacy care, as compared to the conventional model. Patient experience will be reported, and differences in interim data (impact on quality of life) and final health outcomes will be provided.

### Appendix 1

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