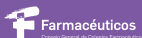


Practical guide

to Clinical Professional Pharmacy Services
(CPPS) in Community Pharmacy



**Foro de Atención
Farmacéutica**
Farmacia Comunitaria



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01 Introduction

This practical guide to **Clinical Professional Pharmacy Services (CPPS)** updates the practical guide published in 2010¹ and aims to promote the objectives established in the 2008² Pharmaceutical Care Forum Consensus Document, specifically directed at the Community Pharmacy.

1. Pharmaceutical Care Forum in Community Pharmacy, expert panel. Practical Guide to Pharmaceutical Care Services in Community Pharmacy. Madrid: General Pharmaceutical Council of Spain; 2010.
2. Pharmaceutical Care Forum, expert panel. Consensus Document, Madrid: General Pharmaceutical Council of Spain; 2008.

The General Pharmaceutical Council of Spain, the Pharmaceutical Care Spain Foundation, the Spanish Society of Family and Community Pharmacy (SEFAC), the Pharmaceutical Care Research Group (GIAP) of the University of Granada and the National Conference of Deans come together to form this working group known as the **Pharmaceutical Care Forum in Community Pharmacy** (Foro AF-FC). Following the creation of this edition, the Forum hopes to achieve maximum diffusion of the adopted resolutions for complete implementation of Professional Pharmacy Services (**CPPS**).

Community Pharmacy (CP) is emphasizing the development of CPPS focused on patients requiring medicines and medical devices, for which a consensus on terminology and procedures needs to be reached.

Our challenge is to disseminate this publication to all community pharmacies, both those that have already begun to implement care practices as well as those that have yet to carry out these services.

In using an agile, didactic, accessible and easy-to-read text we aim to:

- To maintain and disseminate our commitment to Clinical Professional Pharmacy Services in Community Pharmacy.
- To achieve widespread dissemination of the general message.
- To standardize the use of established procedures for each of the CPPS.
- To strengthen efforts to develop applications to be integrated within Professional Pharmacy Services in management systems.
- To facilitate access to tools that offer increased care quality.
- To improve communication and dissemination of topics of interest for the service development and the implementation of Pharmaceutical Care Services to community pharmacists.
- To propose joint actions that will serve to spread a stable image favoring the widespread use of CPPS in current and future professional services.

This is the commitment shared by all of the organizations coming together in Foro AF-FC



Mr. Jesús Aguilar
President of the General Pharmaceutical Council of Spain



Mr. Jesús Gómez
President of SEFAC



Ms. Mercé Martí
President of the Pharmaceutical Care Spain Foundation



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Head of the Research Group in Pharmaceutical Care of the University of Granada



Ms. Beatriz de Pascual
President of the National Conference of Deans

Madrid, 19 November 2019.

02 Justification

As part of the National Health System, pharmacists share with patients, physicians, other healthcare professionals and authorities the mission of ensuring the safe, effective and efficient use of medicines. In this multidisciplinary environment, pharmacists provide knowledge and skills regarding pharmacotherapy and its objectives, thereby improving the quality of life of patients.

This approach responds to the demands of a society an increasingly concerned about achieving your well-being, informed and trained in all aspects related to the concept of health.

Pharmacists, with their training and experience, are involved in healthcare processes related to medicines, since the necessity, effectiveness and safety of medicines do not depend on manufacturing quality alone.

The importance of this is clearly revealed in epidemiological data. According to the World Health Organisation (WHO) report in 2003, over half of all patients suffering from chronic illnesses do not properly adhere to their prescribed treatment.^{3,4} In Spain for example more than half of chronically ill patients do not adequately adhere adequately to the prescribed treatment.⁵ One third of all emergency room visits are the result of negative outcomes related to medicine, of which more than 70% are avoidable.⁶

Pharmacists may facilitate appropriate therapeutic outcomes and help to prevent or resolve the occurrence of Drug-Related Problem (DRP) and Negative Outcomes Associated with Medications (NOM).⁷

3. WHO. Adherence to long-term therapies. Evidence for action. Geneva: World Health Organisation; 2003.
4. Dunbar-Jacob J, Mortimer-Stephens MK. Treatment adherence in chronic disease. *J Clin Epidemiol.* 2001 Dec;54 Suppl 1:S57-60.
5. Martínez-Mir I, Palop V. El problema del incumplimiento terapéutico en diferentes áreas. En: *Cumplimiento Terapéutico.*
6. Drug Related Problems as a cause of consultation in the Emergency Service of the Virgen de las Nieves University Hospital in Granada. [Tesis Doctoral]. Granada: University; 2003.
7. Martínez-Martínez F, Gastelurrutia MA, Varas R, Faus MJ, García MV, Jódar F, et al. Medida del Impacto clínico, económico y humanístico del servicio de seguimiento farmacoterapéutico en mayores polimedicado, en la farmacia comunitaria española. [Internet]. Madrid: CGCOF; 2014. [Acceso 05 noviembre 2019]. Available at: <https://www.farmaceuticos.com/wp-content/uploads/2020/02/2017-Informe-Resultados-conSIGUE-Implantacion.pdf>

Key points

Medicines and Medical devices Dispensing Service (D)

- Dispensing, an essential pharmaceutical practice, **guarantees public access to medicines, offering appropriate information to ensure patient understanding of their correct use of the same, while preventing and correcting specific problems related to them.**
- The active involvement of the pharmacist in Dispensing results in society's perception of medicines as healthcare goods and not as commodities; furthermore, **it contributes to strengthen the patient-pharmacist relationship.**
- **The prescription**, an interprofessional tool and part of the Dispensing process, **is a legal document for dispensing medicines that require it.**

Minor Ailment Service (MAS)

- The Minor Ailment Service is a frequently requested service in Community Pharmacy whereby **the pharmacist, as a healthcare agent, plays a key role in optimizing the use of medicinal products in self-limiting processes, and, in the case of prescribing over-the-counter medicines, it optimises the use of the medication.**
- Some useful tools for the proper handling of typical Community Pharmacy advising situations include developing standardized methodological processes, consensual referral criteria and shared pharmacotherapeutic guidelines.

Medication Review with Follow-up Service (MRF)

- Medicines Review with Follow-up Service is aimed at guaranteeing the appropriate use of medicines and medical devices, according to the clinical needs of each patient.
- **Morbidity and mortality related to the use of medicinal products are major public health problems that may be decreased through the implementation of this service by pharmacists.**
- The Service has demonstrated its impact on patient health outcomes,⁷ it is highly cost-effective⁸ and generating for every euro invested in the MRF Service a benefit of between €3.3 and €6.2 is generated.⁹
- The implementation of this service provides an **opportunity for collaboration between different healthcare professionals to improve patient health**; however it will only be sustainable if remuneration is achieved.¹⁰

Medication Reconciliation Service (MR)

- The Medication Reconciliation Service helps to **identify, classify, evaluate and resolve possible discrepancies** in pharmacological treatment generated in transit between levels of care in the health system.
- The pharmacist's intervention in this service helps to prevent potential harm from the use of medicines. **A critical objective in transitions of care, and especially at the time of hospital discharge, is the maintenance of patient safety.**¹¹

Therapeutic Adherence Service (TA)

- Therapeutic adherence includes both the behaviour of patients in relation to their pharmacological treatments as well as the adherence to hygienic-dietary recommendations or the adoption of lifestyle changes in patients.¹²
- The pharmacist, in collaboration with the patient and other healthcare professionals, can assess, **identify and intervene on problems related to non-adherence in a protocolised and individualised manner.**
- Non-adherence to treatment is a major health and economic problem for health systems today and requires a specific service that has been shown to have a beneficial impact on patient health by helping patients to comply with prescribed treatments.

8. Jódar-Sánchez F, Malet-Larrea A, Martín JJ, García-Mochón L, López del Alamo MP, Martínez-Martínez F, et al. Cost-Utility. Analysis of a Medication Review with Follow-Up Service for Older Adults with Polypharmacy in Community Pharmacies in Spain: The conSIGUE Program. *PharmacoEconomics* 2015; 33(6):599-610. doi: 10.1007/s40273-015-0270-2.
9. Malet-Larrea A, Goyenechea E, Gastelurrutia MA, Calvo B, García-Cárdenas V, Cabases JM, et al. Cost analysis and cost-benefit analysis of a medication review with follow-up service in aged polypharmacy patients. *Eur J Health Econ.* 2017 Dec;18(9):1069-1078. doi: 10.1007/s10198-016-0853-7. Epub 2016 Dec 2.
10. Martínez-Martínez F, Faus MJ, Fikri-Benbrajim N, García MV, Gastelurrutia MA, Malet A, et al. Informe 2014- 2016 conSIGUE: Programa para la implantación y futura sostenibilidad del servicio de Seguimiento Farmacoterapéutico. [Accessed 05 November 2019]. Available at: <https://www.farmaceuticos.com/wp-content/uploads/2020/02/2017-Informe-Resultados-conSIGUE-Implantacion.pdf>
11. Foro de Atención Farmacéutica en Farmacia Comunitaria, panel de expertos. Servicio de conciliación de la medicación en la farmacia comunitaria. [Internet]. Madrid: CGCOF; 2016. [Accessed 05-10-2019]. Available at: <https://www.farmaceuticos.com/wp-content/uploads/2019/12/FOLLETO-CONCILIACION.pdf>
12. Martínez-Martínez F, García MV, Gastelurrutia MA, Varas R, Peiró T, Sáez-Benito L, et al. Informe Global 2019 AdherenciaMED: Diseño, evaluación del impacto e implantación de un Servicio profesional de Adherencia Terapéutica desde el ámbito de la Farmacia Comunitaria. [Internet]. Madrid: CGCOF; 2019. [Accessed 05 November 2019]. Available at: <https://www.farmaceuticos.com/wp-content/uploads/2020/02/2019-informe-resultados-adherenciamed.pdf>

03 Motivation

Current legislation defines the professional pharmaceutical practice, establishing guidelines, functions and mandatory rules regarding **Clinical Professional Pharmacy Services (CPPS)**.

Specifically, article 86 of Royal Legislative Decree 1/2015, of 24 July, on the **rational use of medicines in pharmacies**, establishes that “pharmacists, being responsible for the dispensing of medicines and medical devices to citizens, shall ensure adherence with the guidelines established by the patient’s physician in the prescription, cooperating with said physicians in follow-up treatment through pharmaceutical care procedures, helping to ensure its effectiveness and safety. Similarly, they shall participate in the implementation of a series of activities designed for the rational use of medicinal products, specifically, through informed patient dispensing”.

Over recent years, in response to legislation, major advances have been made in the development of standardized procedures.

While most professionals are involved in activities related to the development of uniform and systemized PPhS, including the subsequent recording of the same. It is necessary to identify the causes leading to changes in pharmacists’ attitudes. Identifying pharmacist needs and achievements in order to modify their behavior will help to achieve the motivation necessary to promote Professional Pharmacy Services.

Benefits for the patient

Improved services

- Patients receive improved care based on their individual needs.
- Clinical Professional Pharmacy Services (CPPS) guarantee uniform and standardized care.
- Quality care in pharmaceutical services is guaranteed, in both public and private settings.
- Access to the community pharmacy network allows for on demand service provision, generating new care habits and demand.

Benefits to society

Optimum use of medicines

- CPPS significantly decrease Problems Related to the use of medicines (DRP), resolving or preventing Negative Outcomes associated with Medications (NOM).
- Healthcare expenses are rationalized, improving adherence, decreasing the number of hospitalizations, increasing the effectiveness of medicinal products and minimizing their possible damage.
- Equality in care service is guaranteed.
- Quality of life is improved.

Benefits to Pharmacy as a profession

Social and institutional recognition

- Evolution towards clinical practice represented by CPPS.
- Social perception of pharmacists as healthcare professionals is improved.
- Through improved pharmacotherapeutic outcomes.

Global redefinition of the professional practice

- CPPS unify the concept of professional practice with the patient.
- Society demands a professional definition that includes Pharmaceutical Care, since personalized services are considered essential.
- Development of the profession is bound to involve the practice of CPPS.
- Progress of the profession is based on Clinical Professional Pharmacy Services.

Opening up new paths for professional development

- The implementation of CPPS creates career expectations in line with the pharmacist's qualification as a healthcare agent.
- The implementation of the CPPS, in collaboration with other health professionals, may favour the perception of specialisation in the Community Pharmacy field.

Benefits to the pharmacist

Professional satisfaction

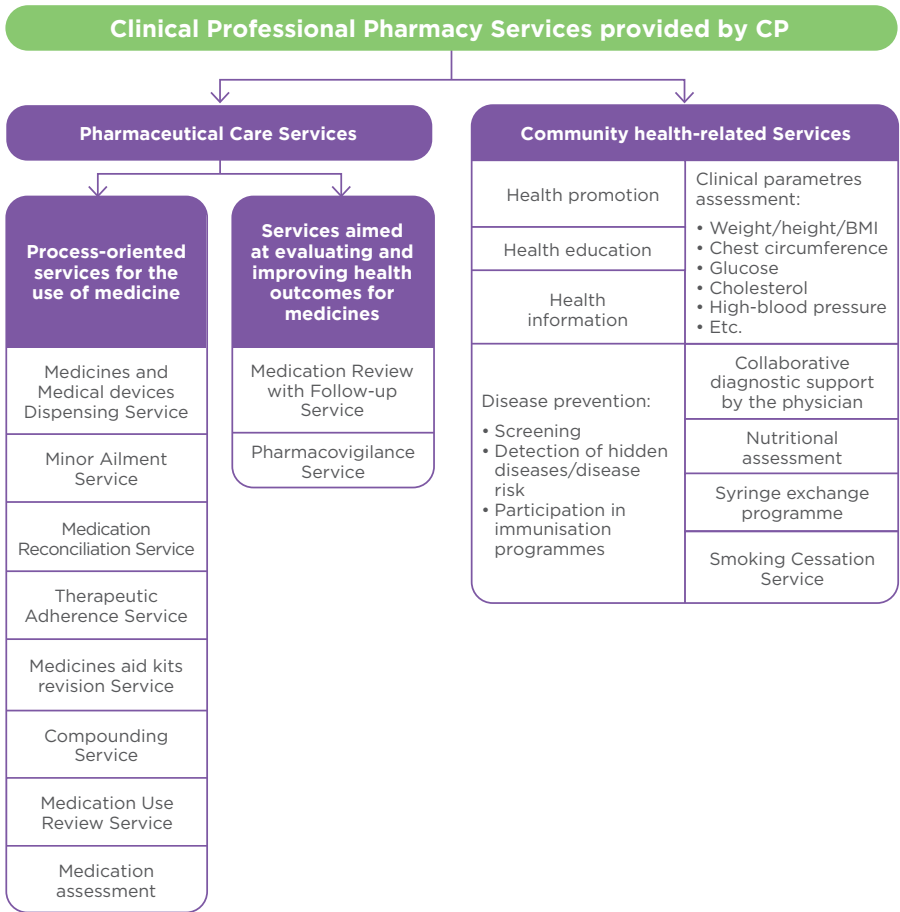
- CPPS represent a more active involvement in patient healthcare processes.
- New and important responsibilities arise, permitting professional development and increased professional recognition.
- Participation in optimal multidisciplinary healthcare teams, facilitating the creation of close and long-lasting bonds between pharmacists, patients and the other healthcare professionals.

04 Definition and general classification of Clinical Professional Pharmacy Services

Foro AF-FC defines CPPS as “those healthcare activities provided from CP by a pharmacist who uses their professional skills to prevent disease and improve both the health of the population and that of the recipients of medicines and medical devices, playing an active role in optimising the process of use and the results of treatments. These activities, aligned with the general objectives of the health system, have their own entity, with their own definition, aims, procedures and documentation systems, which allow them to be evaluated and remunerated, guaranteeing their universality, continuity and sustainability”.

Community Pharmacy (CP) has lead its activity towards patients using medicines. Such use generates great benefits, although, as is well known, every medicine has its adverse/side effects, and the use of medicines, including their correct use of medicines, always entails potential safety problems.

Currently, Foro AF-FC has defined, described and classified a significant number of CPPS (**Figure 1**).



*This classification does not exclude other CPPS that may be considered.

Figure 1. Classification of Clinical Professional Pharmacy Services in Community Pharmacy agreed at the Foro AF- FC

04. Definition and general classification of Professional Pharmacy Services

In order to facilitate the identification of PPhS, Foro AF-FC provides the following checklist:

		YES	NO
1	Is it provided by a Community Pharmacy?	✓	X
2	Is it carried out by or is it the responsibility of a pharmacist?	✓	X
3	Is it a competence of the community pharmacist?	✓	X
4	Does it prevent disease?	✓	X
5	Is it useful for improving the health of the population?	✓	X
6	Does it serve to improve the health of the recipients of the medicines or medical devices?	✓	X
7	Does the pharmacist play an active role in optimising the use process and/or treatment outcomes?	✓	X
8	Is the activity aligned with the overall objectives of the Health System?	✓	X
9	Does it have its own entity, with definition, purposes, procedures and documentation systems, enabling its evaluation and remuneration?	✓	X
10	Does it meet the characteristics of universality, continuity and sustainability?	✓	X

All answers to questions 1, 2, 3, 8, 9 and 10 must be affirmative.

At least one of the answers to question 4, 5, 6 or 7 must be affirmative.

05 Clinical Professional Pharmacy Services

- Medication and Medical devices Dispensing Service
- Minor Ailment Service
- Medication Review with Follow-up Service
- Medication Reconciliation Service
- Therapeutic Adherence Service

MEDICATION AND MEDICAL DEVICES DISPENSING SERVICE

Definition

This is the CPPS offered by pharmacists to ensure, through individual evaluation, that patients correctly receive and use medicines and medical devices, based on their clinical needs, in proper dosages, in accordance with their individual needs, over the appropriate period, receiving the necessary information to guarantee correct usage and in compliance with applicable laws.

To ensure the accessibility and rational use of medicines and medical devices,¹³ hereafter medicines, the pharmacist in the Dispensing Service must take into consideration several data or information related to the recipient of the medicines, for human or animal use, hereafter patients, and their prescription and non-prescription medicines (**Figure 2**).

In this way, the pharmacist, when faced with a medicine request and upon systematic verification that the patient or caregiver has sufficient information for its safe and effective use, may evaluate that this product is appropriate for the patient, and proceed with its delivery, along with the necessary information for its optional use, ensuring access and rational use, in accordance with applicable laws.

Should the request for a medicine be without a prescription (“what can I get for...?”), the process initiated from the Dispensing Service can be transformed into a Minor Ailment Service. Self-medication is defined by the WHO as the “use of medicines to treat self-diagnosed disorders or symptoms”.

Pharmacists, as part of the conversation with the patient, will gather information on what the patient needs the medication for and in your case, if necessary, decide whether this self-medication can be dealt with through the Minor Ailment Service, since the reason for the consultation is focused on the patient's health problem, rather than on the medicine requested. In this service, the pharmacist assesses not only that the medicine is appropriate for the patient, but also that there are no criteria for referral to a doctor, thus increasing safety.

13. Royal Legislative Decree 1/2015, of July 24, approving the consolidated text of the Law on guarantees and rational use of medicines and medical devices. BOE nº 177 (25-07-2015). [Accessed 05 Noviembre 2019]. Available at: <https://www.boe.es/buscar/doc.php?id=BOE-A-2015-8343>.

The objectives of the Medication and Medical devices Dispensing Service are

- To ensure access to the medicinal product and delivering it under optimal conditions, in accordance with applicable laws.
- To ensure patient understanding of how to use the medicinal products and that which it entails.
- To protect patients against the occurrence of NOMs through the identification and resolution of DRPs.
- To refer to other CPPS or healthcare professionals, where appropriate.
- To improve patients' quality of life.

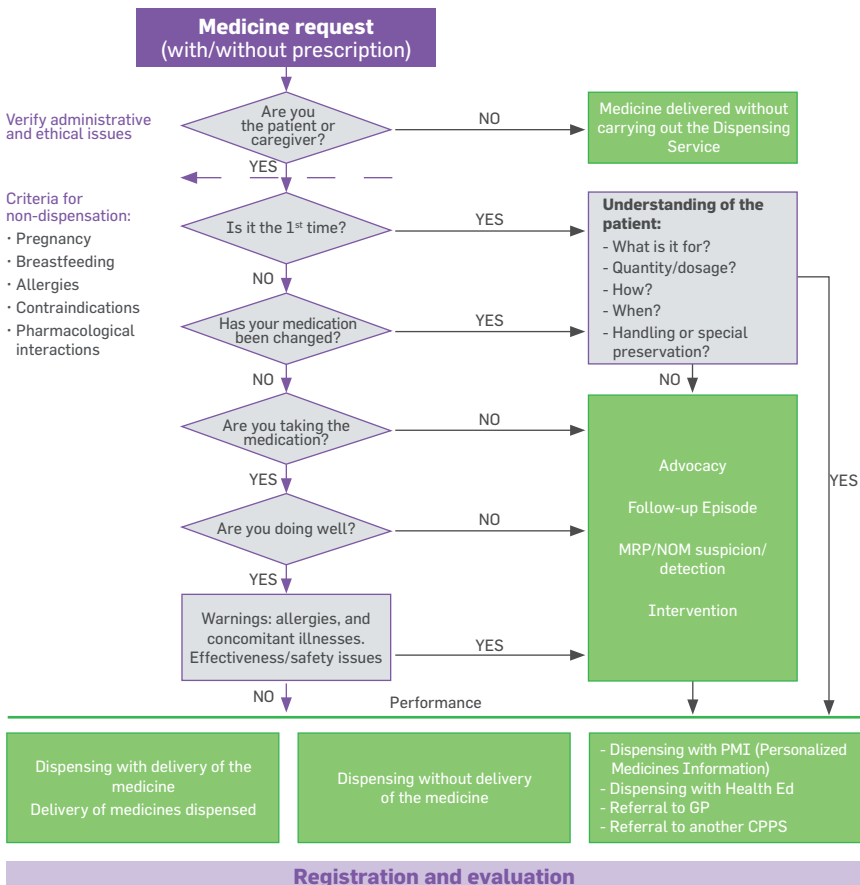


Figure 2. Procedure Diagram of the Dispensing Service for Medicines and Medical Devices

Procedure

Based on the information available at that time, the pharmacist, through an interview, will obtain the necessary clinical information to be able to verify any health-related incidents that would make it unwise dispensing with delivery of the medicinal product.

In case of prescription, such information may be obtained from the prescription itself, from the patient, from the healthcare system with the patient's authorisation or from pharmacy records.

The procedure consists of four steps:

- a) Obtaining information about the patient/caregiver and his/her pharmacotherapy.
- b) Evaluation of information.
- c) Professional performance or intervention, in the event of an Incident.
- d) Recording and evaluation of the Service process.

Upon request for a medicinal product, with or without prescription, the pharmacist should consider:

a) Obtaining information from the patient/caregiver and his/her pharmacotherapy

- **Verify health, ethical and regulatory requirements of the prescription and/or medicines requested without a medical prescription.**

- **Who it is for (the applicant):**

Own use, caretaker, third party. The party receiving the medicinal product shall be identified anonymously, considering their gender, real/approximate age, and relationship to the individual requesting the medication. They may also be identified in a personalized manner.

- **Verify non-dispensing criteria:**

The pharmacist may verify whether or not other medicines are being taken, if there are any concomitant illnesses or allergies that may affect the treatment objectives and the patient health. These may include the following:

- Pregnancy.
- Breastfeeding.
- Allergies.
- Contraindications with illnesses or health problems.
- Pharmacological interactions that pose a contraindication or high risk to the patient's health.
- Unintended duplications.
- Other relevant physiological situations.

05. Professional Pharmaceutical Care Services

In the case of the request for a non-prescription medication that requires it, it will be referred to the doctor and to the Minor Ailment Service may be considered.

If there are no Incidences related to the verification of ethical and regulatory issues that impede dispensing, begin the Dispensing procedure, in accordance with whether it is the first time that the medicinal product has been used.

• **If it is the first time being used. First dispensing treatment:**

The pharmacist, through a short interview, shall obtain key clinical information to determine whether the patient or caretaker understands the medicine usage process, posing the following questions:

- Do you know what it is used for?
- Do you know how much should be taken?
- Do you know for how long it should be taken?
- Do you know how to use it? (determine whether there are special conditions for use/handling and/or storage)
- Do you know the warnings for safety and ineffectiveness?

The pharmacist will be able to address safety and ineffectiveness warnings, along with any expectations of the medicine.

• **If it is not the first time that it is being used. Continued treatment:**

The pharmacist, through a short interview, shall obtain key clinical information in order to evaluate the patient's perception regarding the safety and effectiveness of the medicine, posing the following questions:

- Are you taking your medication as prescribed by your doctor?
- Have any changes been made? (treatment, dosage, etc.)
 - If the response is affirmative, the same questions should be asked as when first dispensing treatment
 - If the response is negative, ask: How is treatment going? and Do you have any problems with the treatment?

Similarly, any necessary biomedical information shall be collected (clinical analyses, blood pressure, etc.), if available.

In order to detect Incidences, the information obtained shall be complemented, with clinical information available through the health system, if available.

b) Evaluation of information

There are occasions when the patient may report a situation where new symptoms or signs, non-adherence to treatment, lack of adherence to treatment, lack of use of inappropriate doses may arise. These are unexpected situations or events that interrupt the natural course of the Service process in what is referred to as identifying an Incident.

A Follow-up Episode is a process of evaluation of potential DRPs and/or NOMs. Following this approach, Foro AF-FC aims to enable untrained pharmacists in the practice of MRF Service to approach it using its tools. The MRF Service is a CP Service oriented towards the evaluation of health outcomes. Studies have shown that it is an efficient and effective service that can be widely implemented in practice and is highly cost-effective. However, the Foro AF-FC is aware of the difficulty involved in its implementation, as it is a Service that is qualitatively different from those that pharmacists have been developing throughout the history of the profession. For this reason, and in order to facilitate the gradual introduction of the MRF Service in practice, the opening of several episodes is proposed as a mechanism for gradually approaching the MRF Service. In fact, there will be patients for whom only one Follow-up Episode will be carried out, while in other cases more than one episode may be carried out on the same patient. In these cases, by performing several consecutive episodes over time, the pharmacist can intuitively and easily incorporate the patient into the MRF Service (**Figure 3**).

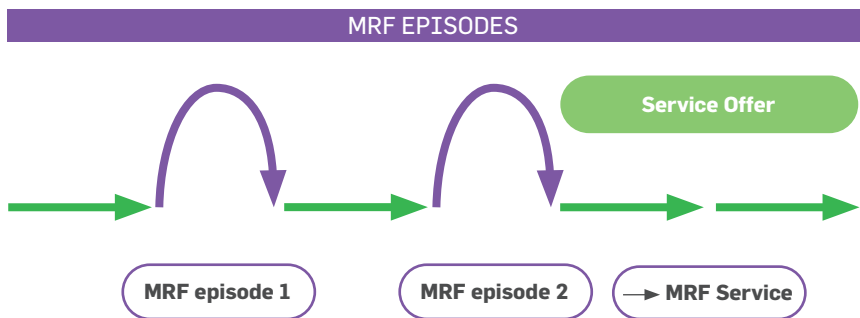


Figure 3. Consecutive MRF episodes

Incidence

This is any circumstance relating to the pharmacotherapy that, during the established dispensing procedure, is not consistent with the accepted or expected situation and that interrupts the procedure, requiring its follow-up evaluation.

In the identification of incidences, the assignment of DRPs to the categories on the list is not exclusive, so that a given incidence can be assigned one or more. It is not exclusive either, so that more categories may be included depending on the different situations that the pharmacist may encounter in their daily practice.

The pharmacist will be able to identify if the patient is in pain, at risk of suffering a health problem as a consequence of the use or disuse of medicines, which prevents the patient from achieving the objective of the pharmacotherapy, and will thus be

05. Professional Pharmaceutical Care Services

detecting a treatment outcome that is not related to the objective set by the prescriber, i.e. a Negative Outcomes Related to Medicines (NOM). NOMs are uncontrolled health problems that may have one or several causes, i.e. one or several DRPs.

LIST OF DRP (NON-EXCLUSIVE AND NON-EXCLUDIBLE)

- Incorrect administration of the medicine.
- High probability of adverse effects.
- Personal characteristics.
- Inadequate conservation.
- Contraindications.
- Temporary lack of supply.
- Inappropriate dosage, treatment and/or duration.
- Duplicities.
- Dispensing errors.
- Prescription errors.
- Errors in the use of medication.
- Lack of reconciliation between levels.
- Lack of knowledge of the use of the medicine.
- Interactions with other medicinal products, medicinal plants, food supplements.
- Medication not required.
- Not taking medication/lack of adherence.
- Other health problems affecting treatment.
- Caution in use.
- Inadequately treated health problem.
- Others.

FORO AF-FC DIVIDES THE NOMS INTO THREE CATEGORIES

- Need.
- Effectiveness.
- Safety.

In turn, each of these categories is divided into:

- Need for medicine (untreated health problem).
- No need for medicine (effect of an unnecessary medication).
- Non-quantitative ineffectiveness.

- Quantitative ineffectiveness.
- Non-quantitative safety risk.
- Quantitative safety risk.

c) Professional performance or intervention, in case of an incidence

In the case of an incidence, the pharmacist will assess the situation with the information obtained in order to carry out the professional performance and the corresponding intervention.

Professional performance

This is the action that the pharmacist takes after carrying out the Service's procedure and will consist of delivering or not delivering the medicine.

Delivery of the medicine

The pharmacist's action shall consist of dispensing with or without delivery of the medicinal product.

In the case of dispensing with delivery of the medicinal product, appropriate anti-counterfeiting checks shall be carried out, if necessary:

- 1- Visual inspection of the packaging to verify that the tamper-evident device is intact.
- 2- Verify and deactivate the Datamatrix code that individually identifies the packaging and allows to verify its authenticity.

In the case of prescription dispensing, the pharmacist shall inform the healthcare professional responsible for the prescription, through the appropriate procedures, of the Incidences detected, the intervention(s) proposed and, where appropriate, the decision to deliver or not to deliver the medicinal product.

The delivery of medicines via ATMs -automated teller machine-, robots, drones, home deliveries, etc. can speed up, but not replace, the necessary checks to be carried out at the Dispensing Service with the patient. In a similar way, it is necessary to have the active participation of the patient so that the service can be carried out completely and with full health guarantees.

Non-delivery of the medicine

The patient will be informed and referred to the appropriate health professional or CPPS.

If no incidences are detected, or if they can be resolved at the premises, the pharmacist's performance will consist of delivering the medication with sufficient Personalized Medication Information (PMI) for responsible use, in accordance with current regulations, with health education, etc.

Intervention

Actions directed to the modification of certain treatment characteristics, for the patient utilizing it or the usage conditions, with the goal of resolving DRPs/NOMs.

If an Incidence is detected, a Follow-up Episode should be opened and studied, so that the pharmacist may to intervene and propose one of the following interventions.

List of possible interventions:

- Provide PMI (Personalized Medicine Information).
- Offer healthcare education.
- Refer to another CPPS.
- Refer to the Primary Care Physician (PCP) communicating the DRP/NOM.
- Refer to the PCP proposing changes in treatment.
- Propose other modifications.
- Notify to the competent pharmacovigilance authority in accordance with the law.

d) Registration of the Service process

As part of the Service process, the pharmacist will record and/or document the professional activity carried out, the identification of Incidences, the interventions and actions performed. In addition, the pharmacist will record the result obtained in the patient's health (improvement, worsening, the same). This will also allow for the evaluation of the Service.

The pharmacist must inform the patient of the functioning of the Service and, in the event that patient data is recorded, must comply with the requirements of the personal data protection regulations, General Data Protection Regulation (GDPR)¹⁴ and Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD),¹⁵ which, among others, requires prior information on the purpose for which the data are collected and the processing that is going to be carried out on them, as well as the fact that you may at any time exercise your rights of access, rectification, deletion, opposition, portability and limitation of the processing of your personal data.

Pharmacy services do not require formalized written consent within the scope of healthcare consent (Law 41/2002); verbal consent would suffice. However, considering that many of them are not widely known by the population, as well as their novel nature and that they require the collaboration of the patient for their provision, written form may be advisable in certain cases, since the latter reinforces the information provided, the transparency and the guarantees for both the patient and the pharmacist in the event of a claim.¹⁶

The registration of the Service should be an automated process, carried out throughout the whole process, in which the following information is recorded:

- Patient data: first name/ surname, health card number, National Identity Card, if applicable, age range or year of birth, gender, special physiological situation, allergies, intolerances, Health Problem (HP), biomedical data, other concomitant medication/treatment.
- Identification of the person collecting the medicinal product, if different than the patient.
- Data on the medicine requested: National Code, units/quantity dispensed, contribution.
- Service data: date, time, pharmacist responsible, dispensing/non-dispensing (action), Incidences detected (DRP, NOM, intervention/s carried out), health outcomes (if possible).
- Outcome of the intervention.

14. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) Official Journal of the European Union, No. L 119 (04-05-2016). [Accessed 05 November 2019]. Available at: <https://eur-lex.europa.eu/eli/reg/2016/679/oj>
15. Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights. BOE, nº 294 (06-12-2018). [Accessed 05 November 2019]. Available at: <https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673>.
16. Baixauli VJ, Abellán-García F, Molinero A, Prats R, Plaza J, Gaztelurrutia L, et al. Patient information on professional pharmaceutical care services in community pharmacy. *Community Pharmacists*. 2019; 11(3):22-41 DOI: 10.5672/FC.2173-9218. (2019/Vol11).003.05.

MINOR AILMENT SERVICE

Definition

This CPPS is provided upon patient request in the pharmacy, when unsure of which medicinal product to acquire and upon requesting that the pharmacist provide the most appropriate remedy for a specific health problem. If the service requires the dispensing of a medicinal product, it shall be carried out in accordance with the previous definition.

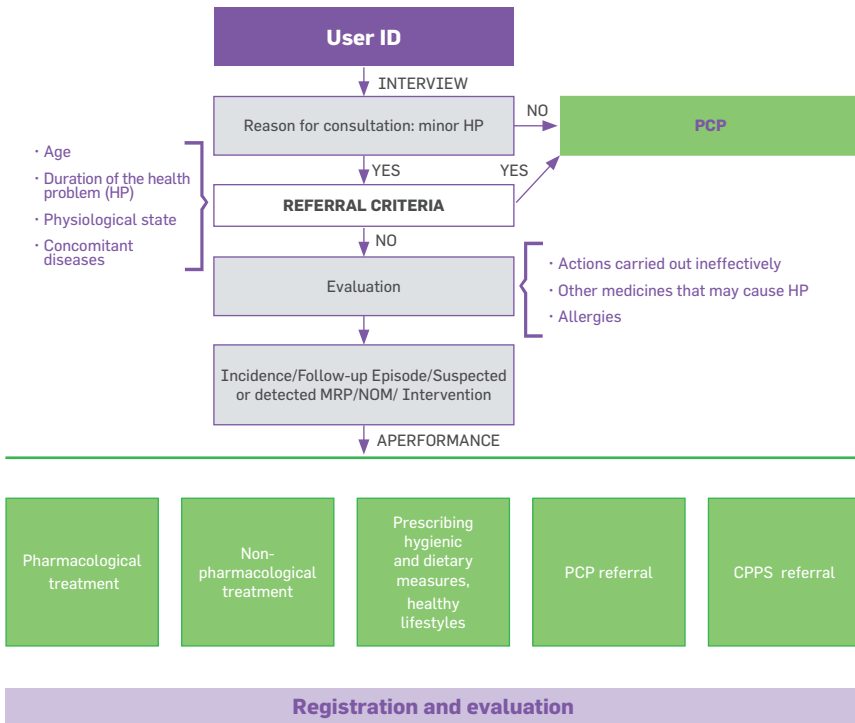


Figure 4. Diagram of the Minor Ailment Service procedure

To offer a professional response to a user request for pharmaceutical advising, the pharmacist should consider certain information or data regarding the patients, their health status and their medicinal products (Figure 4).

Objectives of the Minor Ailment Service

- To assess whether the HP for which the patient or caregiver is consulting is a minor symptom or banal disorder.
- To determine whether the HP referred by the patient is an NOM.
- To protect the patient from the occurrence of NOMs through the identification and resolution of DRPs.
- To identify additional needs to offer other CPPS, if necessary.
- To indicate the most appropriate method of resolving the patient's health problem and, when necessary, to select a medicine, ensuring that the patient knows how to use it and what it entails.
- To resolve any doubts/information gaps that the patient/caregiver may rise and/or lack of information detected by the pharmacist.
- To improve the quality of life of patients.

Procedure

The procedure consists of four steps:

- a) Interviewing the patient.
- b) Evaluation of information.
- c) Performance or intervention, in case of an Incidence.
- d) Recording and evaluation of the Service process.

a) Interview the patient

Patients will be interviewed at the counter or in the Personalised Care Zone (PCZ) in those cases where the patient's privacy may be compromised in obtaining information.

Upon request for a remedy to alleviate a HP, the pharmacist, through the information obtained from an interview with the patient in which the necessary information is gathered (pharmacotherapy, physiological states, concomitant health problems, etc.) should consider:

Who is conducting the consultation? (PA)*:

The reason for consultation may be made by the own patient, the caregiver or a third person on behalf of the patient. The subject making the consultation shall be identified anonymously or in a personalised manner, considering gender, actual/approximate age, and relationship to the person for whom the action is intended. In the case of a third party, the Service procedure can only be carried out if the third party has the information to be assessed by the pharmacist. Otherwise, it cannot be carried out.

What is the reason for the consultation (SY)*:

The health problem (HP) described by the patient. It should be said that it must be a minor symptom (otherwise, always refer to physician). A minor symptom is a HP that is not serious, self-limiting, of short duration, that does not require a medical diagnosis and is not related to other HP and treatments of the patient, and that responds to or is relieved by a treatment that does not require a medical prescription.

- If the HP is the adverse effect of a previously used medication, the corresponding intervention will be carried out and pharmacovigilance will be notified and a Follow-up Episode may be opened.

Verify:

- Duration of the health problem is excessive (T)*.
- Any previous actions taken to try to solve the health problems? (*Have you used anything?*) (A)*.
- Other medicines used for other HP (M)*.
- Known allergies and intolerances (A)*.
- Other concomitant illnesses or a special physiological situation, pregnancy/lactation (E)*.

Lifestyle habits and/or biomedical data, if necessary.

* Acronym used in the procedure:¹⁷

PA: Who

SY: Symptom

T: Time

A: Actions carried out

M: Medicines

A: Allergies

E: Pregnancy or concomitant illnesses

17. Pharmaceutical Consultation in Community Pharmacy. [Doctoral Thesis]. Alcalá de Henares: University of Alcalá; 2001.

b) Evaluation of information

The pharmacist will use the information obtained from the interview to evaluate the verifications performed, identifying whether or not there are criteria for referral to the physician or if NOM and/or DRP have been identified, intervening accordingly.

Evaluate:

- Referral criteria.
- DRPs.
- NOMs.

If an Incidence is detected, a **Follow-Up episode** should be opened, as described on the Dispensing Service, using the lists and consequent classifications, differentiating the type of intervention.

Category assignment based upon the incidences list is not exclusive; therefore a determined incidence may be assigned to more than one DRP. The list is not exhaustive, in that there may be additional categories based on different situations encountered by the pharmacist in his/her routine practice.

The pharmacist may identify whether the reason for consultation arises from the use or disuse of medicines, thereby preventing to achieve the pharmacotherapy objective and detecting a treatment outcome that is not the objective of the prescribing physician, in other words, a NOM. NOMs are uncontrolled health problems that may be caused by one or more causes, i.e., one or more DRP.

LIST OF DRPS (NON-EXCLUSIVE AND EXCLUDIBLE)

- Medication administration error.
- Strong probability of adverse effects.
- Personal characteristics.
- Inappropriate storage.
- Contraindication.
- Temporary lack of supply.
- Inappropriate dosage, treatment and/or duration.
- Duplicities.
- Dispensing errors.
- Prescription errors.
- Lack of reconciliation between care levels.
- Lack of knowledge of the use of the medicine.
- Interactions with other medicinal products, medicinal plants, food supplements.
- Medication not required.
- Not taking medication/lack of adherence.
- Other health problems affecting treatment.
- Caution in use.
- Other inadequately treated health problems.
- Others.

FORO AF-FC FORUM DIVIDES NOMS INTO THREE CATEGORIES

- Need.
- Effectiveness.
- Safety.

Each of these categories, in turn, is divided into:

- Need for medicine (untreated health problem).
- No need for medicine (effect of an unnecessary medication).
- Non-quantitative ineffectiveness.
- Quantitative ineffectiveness.
- Non-quantitative safety risk.
- Quantitative safety risk.

c) Performance or intervention, in the event of an incidence

Performance

Depending on the evaluation of the information collected, the pharmacist's action will be:

- Recommended a pharmacological treatment that does not require a prescription (following the procedure of the Dispensing Service) and can provide information on the medicine, health education.
- Recommended non-pharmacological treatment (may provide information).
- Recommended hygienic-dietary measures, health education and/or health recommendations, healthy lifestyles.
- Refer to PCP or other health professional.
- Refer to another CPPS.

Intervention

If DRPs/NOMs are identified, the intervention to resolve them will be in line with the proposed list.

Foro AF-FC proposes the following list of possible interventions:

- Provide information.
- Offer healthcare education.
- Refer to another CPPS or other healthcare professional.
- Refer to the physician communicating the DRP/NOM and/or proposing changes in treatment.
- Propose other modification.
- Notify the pharmacovigilance systems in accordance with the law.

d) Registration of the Service process

As part of the Service process, the pharmacist will record and/or document the interventions and actions taken. In addition, the pharmacist will record the outcome of their intervention on the patient's health, if possible (improvement, worsening). This will also allow for the evaluation of the Service.

05. Professional Pharmaceutical Care Services

In the event that patient data is recorded, pharmacists must inform the patient of how the Service works and must comply with the requirements of the personal data protection regulations, General Data Protection Regulation (GDPR)¹⁴ and Spanish Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights (LOPDGDD),¹⁵ which, among others, requires prior information on the purpose for which the data are collected and the processing that is going to be carried out on them, as well as the fact that you may exercise your rights of access, rectification, deletion, opposition, portability and limitation of the processing of your personal data at any time.

Within the scope of consent to pharmaceutical care (Law 41/2002), pharmaceutical services do not require formalised written consent; verbal consent would suffice. However, taking into account that many of them are not widely known by the population, as well as their novel nature and that they require the patient's cooperation, written consent may be advisable in certain cases, as it reinforces the information provided, the transparency and the guarantees for both the patient and the pharmacist in the event of a complaint.¹⁶

The registration of the Service should be an automated process and carried out throughout the whole process, in which the following information is recorded:

- Gender and age of patient.
- Reason for consultation.
- Previous actions taken by the patient, relative and/or caregiver.
- Proposed intervention if necessary.
- Action by the pharmacist including the prescribed treatment.
- Health outcomes (if possible).
- Outcome of the intervention.

It is recommended to have the following elements in place to provide the Minor Ailment Service:

- Protocols or guidelines for the treatment of minor health problems.
- Referral documents/reports.
- System for recording the documentation generated in the Service: actions, referrals, interventions, etc., associated with the actions/interventions carried out, allowing the activity to be measured.
- Pharmacotherapeutic guidelines for pharmacy use.

14. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) Official Journal of the European Union, No. L 119 (04-05-2016). [Accessed 05 November 2019]. Available at: <https://eur-lex.europa.eu/eli/reg/2016/679/oj>.
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16. Baixauli VJ, Abellán-García F, Molinero A, Prats R, Plaza J, Gaztelurrutia L, et al. Patient information on professional pharmaceutical care services in community pharmacy. *Pharmaceutics*. Community Pharmacists. 2019; 11(3):22-41 DOI: 10.5672/FC.2173-9218. (2019/Vol11).003.055.

MEDICATION REVIEW WITH FOLLOW-UP SERVICE

Definition

This is the CPPS having the goal of detecting Drugs Related Problems (DRP), for the prevention and resolution of Negative Outcomes Related to associated with Medications (NOM). This Service requires considerable commitment and should be provided on a continual basis, in a systemized and documented manner, in collaboration with the patient and other healthcare professionals, in order to attain specific outcomes that will improve the patient's quality of life.

To offer the Medication review with Follow-Up Service, the pharmacist should maintain a working system that allows for thorough knowledge regarding a series of personal and health data for the patient.

For this, the pharmacist shall maintain a series of personal interviews, in order to establish a professional relationship focused on the pharmacotherapy and the patient's described health problems, in order to achieve optimal results and, when necessary, shall act to correct any detected or potential DRPs or NOMs.

The objectives of the Medication Review with Follow-up Service are the following:

- To detect, identify and resolve MRP/NOMs, for the resolution and prevention of NOMs.
- To maximise the efficiency and safety of the treatments, minimising the risks associated with them.
- To rationalize medicinal products use, improving their use.
- To improve the quality of life of patients.

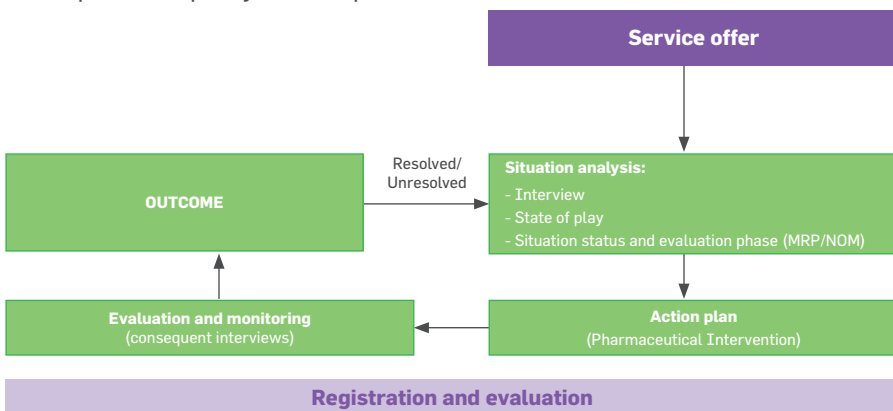


Figure 5. Flowchart of the Medication Review with Follow-Up Service procedure

Procedure

The basic plan (**Figure 5**) for conducting Medication Review with Follow-up Service should always consider the following aspects:

- a) Service Offering.
- b) Situation analysis:
 - Interview for basic information collection.
 - Determination of the situation status (medicinal products and health problems/ biological parameters).
 - Study phase.
 - Evaluation phase for identification of potential DRP/NOM.
- c) Pharmaceutical action and action plan, if necessary.
- d) Evaluating and monitoring the outcomes of the pharmaceutical intervention (acceptance and health outcomes).
- e) Registration of the Service process.

a) Service offering

Since the CPPS is not widespread and is unknown to most patients, demand for it is low in practice. It is therefore necessary for pharmacists to offer the service to patients who are likely to receive it, explaining the health service they will receive: what it is, what it aims to achieve and its main characteristics.

All patients using at least one medicine can benefit from this service. However, there are groups of patients who may benefit more, such as patients with a chronic disease or those with specific characteristics or who use medicines with a narrow therapeutic margin, special medical control or hospital diagnosis.

b) Situation analysis

1. Interview for basic data collection

Once the patient has decided to participate in the Service, he/she is called for a first interview, asking him/her to bring a bag with all the medications he/she uses or has at home first aid kit (brown bag). It is important to insist that all medicines are present, including those products that patients sometimes do not understand as medicines, such as lotions or shampoos, homeopathic products, vitamins, etc.

By means of a personal interview in a specially prepared area (Personalized Care Zone [PCZ]), patient information' will be collected and common pharmacy tools will be used, such as devices (i.e. blood pressure monitors, glucometers, cholesterol meters, etc.) and other sources of information, such as clinical practice guidelines, medicines data sheets, etc.

The pharmacist should use open-ended questions and proceed with the interview in a systematic way.

Information that the pharmacist should obtain in the initial interview with the patient should include:

- Who the patient is, personal and health data, case history, special physiological situation.
- Medicines that the patient uses or have used in the past, checking the following items:
 - The name of the medicinal product (National Code), if it exists.
 - The start date of treatment.
 - The prescribed/indicated dosage and the one used by the patient.
 - The prescriber.
 - Dosage and daily dose.
 - Type of treatment, sporadic or not, active or not.
 - Knowledge of and adherence to treatment.
 - Duration of treatment.
- Health problems reported by the patient, as well as their degree of concern, awareness and control.
- Biological parameters (clinical analyses, anthropometric values, etc.).
- Allergies and intolerances.
- Special physiological states.

2. State of play

Based on these data, the pharmacist will produce the patient's status, relating each medicine to the disease or health problem referred, considering other data such as biological parameters.

The Situation Status Form is a document that shows, as a summary, the relationship between the patient's HPs and medications at a specific date. It is a tool that makes it possible to analyze the "photograph" of the patient at a given time.

Health Problems			Medicines				Evaluation							
Starting Date	Health Problem	Control	Starting Date	National Code	Active ingredient and dose to be taken	Prescribed dosage	Used dosage	DRP	N	E	S	NOM		
		<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Don't know										<input type="checkbox"/> NOM <input type="checkbox"/> Risk of NOM <input type="checkbox"/> No NOM	<input type="checkbox"/> No need <input type="checkbox"/> Need <input type="checkbox"/> Ineffectiveness <input type="checkbox"/> Insecurity	
		<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Don't know										<input type="checkbox"/> NOM <input type="checkbox"/> Risk of NOM <input type="checkbox"/> No NOM	<input type="checkbox"/> No need <input type="checkbox"/> Need <input type="checkbox"/> Ineffectiveness <input type="checkbox"/> Insecurity	
		<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Don't know										<input type="checkbox"/> NOM <input type="checkbox"/> Risk of NOM <input type="checkbox"/> No NOM	<input type="checkbox"/> No need <input type="checkbox"/> Need <input type="checkbox"/> Ineffectiveness <input type="checkbox"/> Insecurity	
		<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Don't know										<input type="checkbox"/> NOM <input type="checkbox"/> Risk of NOM <input type="checkbox"/> No NOM	<input type="checkbox"/> No need <input type="checkbox"/> Need <input type="checkbox"/> Ineffectiveness <input type="checkbox"/> Insecurity	
Parameters and observations														

Figure 6. Situation Status data collection form

3. Study phase

Upon analysis of the initial situation, the next stage of the process begins, the study phase, which aims to deepen the knowledge on HP and medicines. In this way, the pharmacist will study each medicine (dose, regimen, mechanism of action, etc.) and its relationship with the health problem being treated. The pharmacist will start this phase by looking at the health problem of greatest concern to the patient. This phase facilitates the evaluation phase.

4. Evaluation phase

At this stage, the pharmacotherapy is evaluated in relation to the patient's HP, identifying possible DRPs/NOMs or the risk of their occurrence (when the pharmacist identifies a DRP, but no NOM) according to the list and classification of DRPs and NOMs made by Foro AF-FC.

c) Action plan (pharmaceutical interventions)

Based on the analysis of the patient's situation (medicines and HP) and taking into account the control of HP, interventions with the doctor and/or the patient will be considered and implemented.

The pharmacist, in agreement with the patient, will identify the patient's main concerns and will establish with the patient the action plan to be followed to prevent or resolve potential NOM or risk of NOM identified.

Pharmaceutical intervention can be carried out:

- **Direct-to-patient intervention:** Those situations where essential aspects of the pharmacotherapy do not need to be modified. It is only necessary to modify them when changes in the patient's behaviour are required, for example, in the case of non-adherence to treatment, or when the patient has not properly understood aspects related to the process of using the medicine (dosage, regimen, duration or storage of the medicines).
- **In collaboration with the doctor (or other healthcare professional, if applicable).** In some countries pharmacists can prescribe treatments: when essential aspects of the pharmacotherapy need to be modified, such as the addition or elimination of medicines, modification of doses or dosage regimens, etc. In this case, the corresponding doctor or health professional must take the decision to analyse the benefit-risk of the treatment and therefore make the appropriate modifications. In these cases, communication may be done by interview with the doctor (telephone or face-to-face) or in writing (letter or e-mail).

Foro AF-FC proposes the following list of possible interventions to resolve or prevent NOMs:

- Facilitate PMI (Personalized Medicines Information).
- Provide health education/patient education:
 - Educate on the use of the medicine.
 - Changing treatment skills.
 - Educate on non-pharmacological measures.
- Refer to another CPPS.
- Refer to another professional communicating DRP/NOM.
- Refer by proposing changes in treatment:
 - In the pharmacological strategy:
 - Proposal to add a medicine.
 - Proposal to withdraw a medicine.
 - Proposal to replace a medicine.
 - On the amount of medicine:
 - Proposal to modify the dose.
 - Proposal to modify the form and route of administration.
 - Proposal to modify the dosage of administration.
- Propose other amendments.
- Report to pharmacovigilance in accordance with current legislation.

d) Evaluating and monitoring the outcomes of the pharmaceutical intervention

In this phase, observed health outcomes (generally clinical outcomes) are evaluated, although sometimes humanistic outcomes such as satisfaction with the Service or perceived health-related quality of life (HRQOL) can also be evaluated.

The acceptance of the proposed pharmaceutical intervention by the end user, either the patient or the physician, is also evaluated.

e) Registration of the Service process

The MRF Service must be documented as in any clinical practice, and this is a key aspect in the development of this healthcare practice. The pharmacist must have adequate documentation systems in place to record this activity.

The pharmacist should inform the patient about the operation of the Service and, where patient data is recorded, must comply with the requirements under the personal data protection regulations, General Data Protection Regulation (GDPR)¹⁴ and Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD),¹⁵ which, among others, requires prior information on the purpose for which the data are collected and the processing that is going to be carried out on them, as well as the fact that you may at any time exercise your rights of access, rectification, deletion, opposition, portability and limitation of the processing of your personal data.

Within the scope of consent to healthcare (Law 41/2002), pharmacy services do not require formalized written consent; verbal consent would suffice. However, considering that many of them are not widespread by the population, as well as their novel nature and that they require the patient's cooperation, written consent may be advisable in certain cases. In addition, it reinforces the information provided, the transparency and the guarantees for both the patient and the pharmacist in the event of a complaint.¹⁶

On the other hand, only by recording the different process and outcome indicators it is possible to demonstrate how efficient the Service is.

As part of the process, the pharmacist will record the outcome of their intervention, which may or may not be accepted by the patient or physician. In addition, in post-intervention interviews, the pharmacist should record the outcome: resolution of the DRPs/NOMs and action to prevent NOMs and whether there have been any changes in the patient's health status (did it improve?, did it get worse?, did it stay the same?).

The result of this intervention may be:

- Accepted.
- Not accepted.

Where appropriate, it may be evaluated in relation to the NOM:

- Resolved.
- Unresolved.

14. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) Official Journal of the European Union, No. L 119 (04-05-2016). [Accessed 05 November 2019]. Available at: <https://eur-lex.europa.eu/eli/reg/2016/679/oj>.
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MEDICATION RECONCILIATION SERVICE

Definition

This is the CPPS where the pharmacist performs a systematic and protocolised comparison of the list of medicines used by the patient, before and after a transition between levels of care, in order to identify, classify, evaluate and resolve possible discrepancies in coordination, if appropriate, with other healthcare professionals involved.

The objectives of the Medication Reconciliation Service are:

- To detect medication discrepancies.
- To identify and typify the discrepancies detected.
- To clarify/resolve identified discrepancies.
- To optimise available healthcare resources.
- Improve collaboration between levels of care for the benefit of the patient.
- Improve the quality of life of patients.

Procedure

The procedure to be followed after the pharmacist has identified a care transition in a patient is described in **Figure 7** and consists of the following steps:

- a) Service offering.
- b) Patient interview.
- c) Preparation of a complete and accurate list of pre-medication.
- d) Reviewing the new list of prescribed medication.
- e) Comparison of the two medication lists.
- f) Identification, classification, evaluation and resolution of discrepancies.
- g) Communicating the changes.
- h) Recording and evaluation of the Service process.

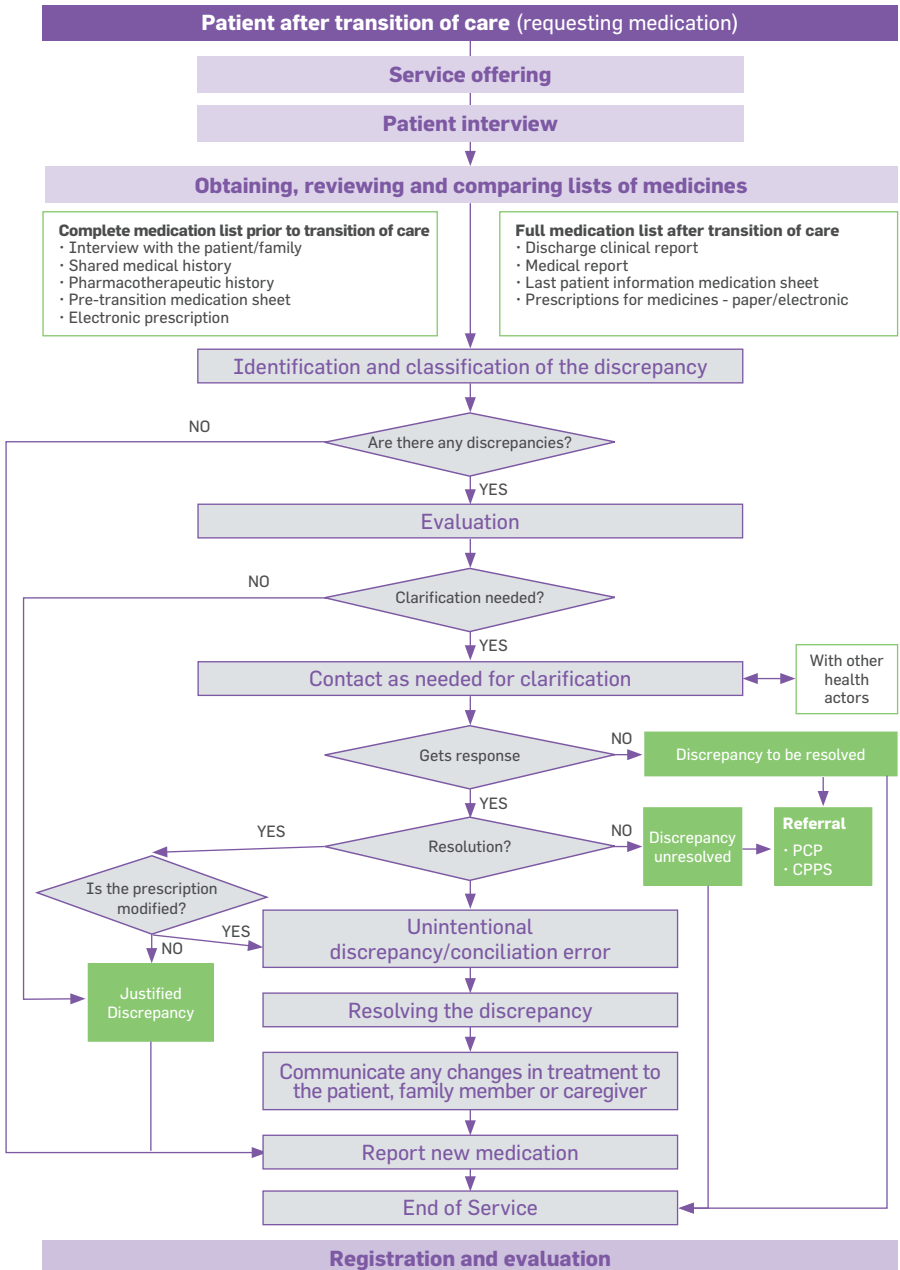


Figure 7. Diagram of the Medication Reconciliation Service Procedure

a) Service offering

Given that it is a little-known service, pharmacists should offer it to patients who are likely to receive it, especially elderly, polymedicated patients, those receiving high-risk medicines, those who are treated by different healthcare professionals and in different centres, as well as the paediatric population.

b) Patient interview

The patient interview will provide information about the patient's pharmacotherapy before and after a care transition.

c) Preparation of complete and accurate list of previous medication pre-medication

The information will be obtained from the patient interview itself, the shared medical record, the pharmacotherapeutic history, the pre-transition medication sheet or the electronic prescription.

This list shall include both prescription and non-prescription medicinal products, vitamins, herbal medicines, etc. As well as the dosage, route and frequency of administration of each medicine.

d) Reviewing of the new prescribed medication list

The clinical discharge report, if applicable, or the medical report issued after a consultation, shall be thoroughly reviewed.

The latest patient information sheet or prescriptions for medicines prescribed either electronically or on paper may also be used.

e) Comparison of the two medication lists

Comparing the two lists will allow the identification of discrepancies that require clarification considering the patient's current clinical situation.

f) Identification, classification, evaluation and resolution of discrepancies

Once discrepancies have been identified, classified and assessed, they should be resolved according to the nature of the discrepancies (please see page 46 for a review of the classification of discrepancies):

- Communicate with the prescriber to clarify unjustified discrepancies (require clarification).
- Refer to doctor/other health professional.
- Refer to other CPPS.

g) Communication of changes

Changes to their new medication should be communicated to the patient, family member or caregiver, preferably with written information about their updated medication.

h) Registration of the Service process

The Reconciliation service must be documented as in any professional pharmacy service, which is a key aspect in the development of this healthcare practice. The pharmacist must have adequate documentation systems in place to record this activity.

Recording the data obtained during the service allows to evidence its performance and to evaluate the impact on the patient and on the healthcare provided.

To be registered:

- The patient's personal and health information.
- Where in the transition of care has the service been carried out.
- Information on the reconciliation: discrepancies and type detected, how they were resolved, whether there was a reconciliation error.

The pharmacist should inform the patient about the operation of the Service and, where patient data is recorded, must comply with the requirements under the personal data protection regulations, General Data Protection Regulation (GDPR)¹⁴ and Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD),¹⁵ which, among others, requires prior information on the purpose for which the data are collected and the processing that is going to be carried out on them, as well as the fact that you may at any time exercise your rights of access, rectification, deletion, opposition, portability and limitation of the processing of your personal data.

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Classification of discrepancies

Reasoned disagreement that does not require clarification

- Medical decision not to prescribe a medicine or to change its dose, frequency or route based on the new clinical situation.
- Medical decision to change the dosage or route of administration of a medicinal product based on the new clinical situation.
- Start of new medication justified by the clinical situation.
- Therapeutic substitution according to current pharmacotherapeutic guidelines and/or therapeutic exchange programmes.

Discrepancy requiring clarification

- Medication omission: the patient was taking a necessary medication and it has not been prescribed without explicit or implicit clinical justification for omitting it.
- Different dose, route or frequency of a medicine: the dose, route or frequency that the patient was taking is changed without explicit or implicit clinical justification.
- Incomplete prescription: the prescription of chronic treatment is incomplete and requires clarification.
- Wrong medicine: a new medicine is prescribed without clinical justification, mistaking it with another medicine that the patient was taking and that has not been prescribed.
- Initiation of medication (commission discrepancy): a treatment is initiated that the patient was not taking before, and there is no clinical justification, either explicit or implicit, for its initiation.
- Duplicity: the patient has a duplicity between the previous medication and the new prescription.
- Interaction: the patient has a clinically relevant interaction between the previous medication and the new prescription.
- Maintains contraindicated medication: a chronic medication contraindicated by the patient's new clinical situation is continued.

Medication omission without clinical justification	Prescribing error/ undertreated HP
Different dosage, route or frequency of a medicine	Inadequate dosage, schedule and/or duration
Incomplete prescription	Prescription error
Wrong medicine	Medication not required
Initiation of medication without clinical justification	Medication not required
Duplicity	Duplicity
Interaction	Interactions
Maintain contraindicated medication	Contraindication

Table 1. Proposed possible relationship between discrepancies and DRPs listing

DEFINITIONS

Transition of care: any transitional situation in which the prescription needs to be reviewed and re-registered. At the hospital level, it includes admission, transfer between services and discharge from hospital; at the outpatient level, it includes home care, emergency care or different medical consultations, as well as changes of address and primary care doctor or admissions to socio-health centres.

Discrepancy: any difference between the usual medication the patient was taking previously and the medication prescribed after a transition of care.

Justified discrepancy (no clarification required): discrepancy that is explained by the information contained in the discharge report or by the information obtained in the interview with the patient, or that requires clarification and the prescriber does not modify the treatment once informed of it.

Discrepancy requiring clarification (not justified): discrepancy that cannot be explained, a priori, by the clinical situation of the patient and requires a consultation with the doctor responsible for the patient.

Unintentional discrepancy or reconciliation error: it discrepancy that requires clarification and after being reported to the physician is corrected in the prescription.

Discrepancy pending resolution: discrepancy that requires clarification, but the prescriber could not be contacted or no response has been obtained.

THERAPEUTIC ADHERENCE SERVICE

Definition

This is the CPPS in which the pharmacist, facing potential difficulties a patient may present in the use of their therapy, identifies the causes, and through their intervention, if necessary, in coordination with other health agents, collaborates with the patient to follow the recommendations on the appropriate process of use of medicines and health devices. This is aligned with the hygienic-dietary habits and/or lifestyle, in order to achieve the expected results of their treatment.

The objectives of the Therapeutic Adherence Service are:

- Improving, reinforcing and maintaining patients' adherence to treatment.
- Increasing patients' capacity to self-manage their treatment.
- Enhancing patients' knowledge of their disease.
- Collaborating with other health agents in the optimisation of available health resources.
- Improving the quality of life of patients.

Procedure

The Therapeutic Adherence Service procedure is described in **Figure 8** and should include the following steps:

- a) Identification of suspected non-adherence.
- b) Service Offering.
- c) Patient interview.
- d) Classification of adherence.
- e) Type of non-adherence and evaluation of non-adherence barriers.
- f) Intervention.
- g) Evaluation of readiness for change.
- h) Adherence monitoring.
- i) Recording and evaluation of the Service process.

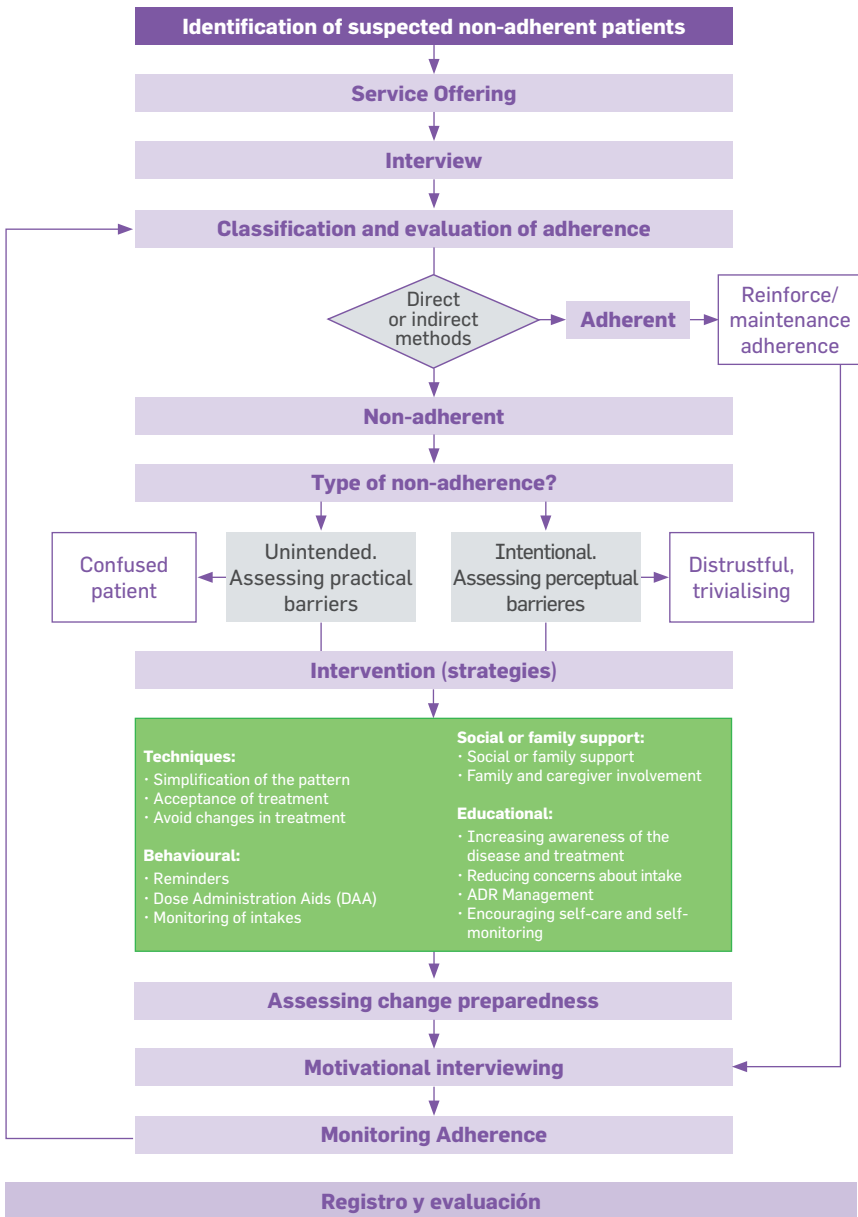


Figure 8. Diagram of the Therapeutic Adherence Service Procedure

a) Identifying suspected non-adherence

Detection may be spontaneous by the patient or caregiver or suspected by the pharmacist or other healthcare professional.

b) Offering of the Service

As it is not a widely known service, pharmacists need to offer it to patients who are likely to receive it, especially elderly patients, patients with multiple medications, patients who are starting or modifying a treatment, patients with high-risk medications, patients with difficulties in administering medication or in following schedules, and patients who are attended by different healthcare professionals.

c) Patient interview

During the patient interview, the pharmacist will assess patient adherence using a combination of different direct/indirect, objective/subjective methods, such as the analysis of dispensing records or the use of validated patient-perceived adherence questionnaires.^{12,18}

d) Classification of adherence

- a. If the patient is adherent, the intervention will focus on reinforcing and maintaining adherence, preventing possible relapses.
- b. If the patient is non-adherent, he/she can be classified as follows:
 - i. Unintentional non-adherence.
 - ii. Intentional non-adherence.
 - iii. Combined non-adherence.

e) Assessing barriers to non-adherence

During the interview, the pharmacist should inquire into the reasons that are influencing or causing non-adherence, which may be either practical barriers (unintentional) or perception barriers (intentional).

f) Intervention

Based on the type of non-adherence, the intervention will be designed and tailored. Individualised strategies will be used. These strategies might include:

- Techniques (i.e. simplification of treatment).
- Behavioural (encouraging patient adherence behaviour change).
- Educational (increasing knowledge about SP and treatment).
- Social and family support (involvement of the patient's environment).

g) Assessing readiness for change

Throughout the Service, readiness for patient behaviour change should be assessed and motivational interviewing skills and principles should be used.

h) Adherence follow-up

Both adherent and non-adherent patients should have their adherence assessed on an ongoing and regular basis.

i) Registration of the Service process and the intervention

The Adherence Service must be documented as in any other CPPS and this is a key aspect in the development of this healthcare practice. The pharmacist must have adequate documentation systems in place to record this activity.

Recording the data obtained during the Service will allow the performance of the Service to be evidenced and the impact on the patient and the healthcare provided to be assessed. The minimum data to be recorded are:

- Patient data: gender, age, necessary clinical information (medications used, health problems, etc.).
- Service data: date, time and staff attending and resolving it, description of the suspected lack of adherence, and classification of adherence, barriers detected and strategies proposed, evaluation, resolution and/or referral.

The pharmacist must inform the patient of the functioning of the Service and, in the event that patient data is recorded, must comply with the requirements of the personal data protection regulations, General Data Protection Regulation (GDPR)¹⁴ and Spanish Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights (LOPDGDD),¹⁵ which, among others, requires prior notification of the purpose for which the data are collected and the processing that will be carried out on them, as well as the fact that you may at any time exercise your rights of access, rectification, deletion, opposition, portability and limitation of the processing of your personal data.

Within the scope of consent to healthcare (Law 41/2002), pharmaceutical services do not require formalised written consent; verbal consent would suffice. However, taking into account that many of them are not widely known by the population, as well as their novel nature and that they require the patient's cooperation, written consent may be advisable in certain cases, as it reinforces the information provided, the transparency and the guarantees for both the patient and the pharmacist in the event of a complaint.¹⁶

05. Professional Pharmaceutical Care Services

Method	Definition	Strength	Limitation
DIRECT METHODS			
Biological Methods.	Medication levels are measured through the monitoring of plasma concentrations.	Standard method.	It is expensive. Invasive method. White coat syndrome.
Collection of clinical and analytical data by direct observation.	Medication is monitored by the professionals who administered it (injectables and inpatients).	Standard method. The exact dose and time of administration is known.	It is expensive. It needs external validation. Ethical conflicts.
INDIRECT METHODS			
Diary.	The patient keeps a diary of the medication he/she is taking.	Economical. It can be used to go deeper with the patient when poor adherence is detected.	External validation required. Patient bias.
Counting of leftover tablets.	The tablets left in the container are counted.	Economical. Standard method.	Professional biases. Patient biases. Not applicable to other dosage forms.
Electronic devices.	Pill dispenser with electronic pill counting device.	Standard method. Adhesion patterns over time.	It is expensive. Not applicable to other dosage forms. Patient biases. Possible technological failures.
Dispensing register with databases.	Databases for pharmacies, hospitals, centres, etc. primary care, emergencies.	Measures no. of units omitted better than questionnaires.	Information bias (overdose, discontinuation of treatment, not really taking it).
Questionnaires.	Through self - or hetero-reported questionnaires.	Low cost. Easy to implement. Reasons provided.	Many questionnaires with low reliability. Memory and response biases.

Table 2. Classification of adherence measurement methods

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06 Indicators

Clinical indicators are commonly used to measure and quantify the safety and quality of care provided to patients, and their definition, in general, can be very heterogeneous.¹⁹

Indicators are useful because they provide a quantitative basis for clinicians (service providers), organisations and managers to improve the care and processes provided to patients. They make it possible to document the quality of care, to benchmark over time between different facilities (i.e. Community Pharmacy (CP), to evaluate and set priorities, to establish regulations and accreditations, to support continuous improvement and to support patients' freedom of choice. In short, monitoring indicators allow professionals and organizations to monitor and evaluate patient outcomes and their consequences.²⁰

While indicators can be classified in various ways, the most common system is based on the analysis of structure, processes and outcomes, as first proposed by Avedis Donabedian.²¹

In this document, the structural indicators have been omitted and the AF-FC Forum focuses primarily on process and outcome indicators.

Structural indicators are those that describe the characteristics that affect the capacity to deliver healthcare in response to patients' needs. Examples of these indicators may include members of the CP staff, people cared for, equipment, available internet access or computers, publications or other sources of information available, investment made, etc. All of these aspects are related to the environment in which the service is to be provided.

One of the main objectives of the Foro AF-FC is to propose agreed definitions and procedures for different CPPS in order to ensure the highest quality of care provided by the Pharmacist. Normally, each CPPS has an operational definition and procedure and should therefore include corresponding lists of indicators to evaluate the provision of the Service (process indicators) and/or the results obtained from it (outcome indicators).

FDA defines **process indicators** as a laboratory measurement or physical sign that is used in therapeutic trials as a surrogate for a clinically meaningful outcome. This is a direct measure of how a patient feels and is expected to be able to predict the effect of therapy.²² This might be an overly clinical definition. In summary, process indicators allow for measuring the quality of the CPPS provided and are used for continuous improvement of professional practice.²⁰

19. Bampoe S, Cook T, Fleisher L, Grocott MPW, Neuman M, Story D, et al. Clinical indicators for reporting the effectiveness of patient quality and safety-related interventions: a protocol of a systematic review and Delphi consensus process as part of the international Standardised Endpoints for Perioperative Medicine initiative (StEP). *BMJ Open* 2018;8:e023427. doi:10.1136/bmjopen-2018-023427.

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Outcome indicators make it possible to measure the effects on health outcomes of different interventions on patients.²³ It is interesting to recall that outcome indicators can in turn be final or intermediate or surrogates. Final or “true” outcomes are becoming increasingly important. Some authors argue that since the real goals of health care are to improve people’s quality of life, to help them live longer and to do so at a reasonable cost, these and only these are the true final outcomes: health status, survival and cost.²⁴ However, intermediate outcomes remain the most widely used because of their immediacy, accessibility and ease of measurement. Yet they remain contested precisely because they are just that, intermediate outcomes, which can lead to misleading conclusions.²⁵ It should also be remembered that a patient may have “poor” health outcomes following exemplary CPPS provision, and conversely, excellent outcomes may be obtained following very poor quality care.²⁶

Traditionally, CP has not recorded its multiple activities, something that needs to change. Therefore, Foro AF-FC intends to progressively develop different indicators as part of the process of recording and subsequent evaluation of data related to CPPS practice and outcomes.

It is important to remember that an indicator should be used for comparison and is therefore usually represented by a formula and in many cases expressed as a percentage. In this formula, the denominator is a variable that allows the comparison to be established, for example in CP it could be: number of prescriptions provided or medications dispensed, performance, pharmaceutical actions or interventions, etc. Another aspect to always bear in mind is the time variable, i.e., that what we are measuring is the day, week or month.

Process indicators

The following are listed indicatively, although there may be many others:

- Number of incidents detected and types (identified DRP) (D, MAS, MRF).
- Number and types of interventions carried out, especially referrals to the doctor (D, MAS, MRF, TA).
- Number of discrepancies and types detected (MR).
- Number of dispensations that end up in the Pharmaceutical Indication Service (D, MAS).
- Number of prescription drugs dispensed (D, MR, TA, MR).
- Number of PS referred (D, MAS, MRF, TA, MR).
- Number of medicines dispensed without prescription (D, MAS, MRF).
- Number of deliverable and non-deliverable dispensations (D, MRF).
- Number of dispensations with substitution of the prescribed medicine and the cause (D, MRF, TA, MR).
- Number and type of communication with the doctor; verbal or written (D, MAS, MRF, TA, MR).

- Acceptance or not of the intervention proposal to the MAP (D, MAS, MRF, TA, MR).
- Primary care visits (MRF, TA, MR).
- Percentage or number of adherent patients (D, MAS, MRF, TA, MR).
- Level of knowledge about medicines (D, MAS, MRF, TA, MR).
- Degree of variation in the number of medicines and associated cost (D, MAS, MRF, TA, MR).
- Cost of pharmacist training (D, MAS, MRF, TA, MR).
- Cost of time spent offering the Service (D, MAS, MRF, TA, MR).

Outcome indicators

- Number of reports to pharmacovigilance system in a period of time (D, MAS, MRF, TA, MR).
- Number, % of ADRs reported over a period of time (D, MAS, MRF, TA, MR).
- Number, % of NOMs resolved after intervention over a period of time (D, MAS, MRF, TA, MR).
- Outcome of the interventions proposed to the MAP with improvement, worsening or maintenance of the patient's health status (D, MAS, MRF, TA, MR).
- Variation in the number of rRNMs/RNMs identified and/or resolved over a period of time (D, MAS, MRF, TA).
- Variation in the number of HP monitored over a period of time (MRF, AT, MR).
- Variation in the number of uncontrolled HP over a period of time (D, MAS, MRF, TA, MR).
- Variation in the number of emergency visits over a period of time (MRF, TA, MR).
- Variation in the number of hospitalizations over a period of time (MRF, TA, MR).
- Variation in the number of MAP visits over a period of time (D, MAS, MRF, TA, MR).
- Satisfaction (D, MAS, MRF, TA, MR).
- Patient-perceived health-related quality of life (MRF, TA, MR).
- Quality-adjusted life years (QALYs) (MRF, TA, MR).
- Amount saved (D, MAS, MRF, TA, MR).

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07 Glossary

Pharmaceutical Care

This is the pharmacist' active participation in improving the quality of life of the patient through Professional Pharmacy Services. It implies cooperation with physicians and other healthcare professionals to achieve results that improve the patient's quality of life, as well as intervention in activities that provide good health and prevent illness.

This is a professional practice in which the pharmacists are responsible for the patient needs regarding medicines.

Clinical Professional Pharmacy Services

These are healthcare activities provided by a community pharmacist who uses his or her professional skills to prevent disease and improve the health of both the population and the recipients of medicines and medical devices, playing an active role in optimising the process of use and the results of treatment.

These activities, aligned with the general objectives of the health system, have their own entity, bearing their own definition, aims, procedures and documentation systems, which allow them to be evaluated and remunerated, guaranteeing their universality, continuity and sustainability.

Medicines and Medical devices Dispensing Service

It is the Clinical Professional Pharmacy Service aimed at guaranteeing, after individual evaluation, that patients will receive and use medicines in an appropriate manner to their clinical needs, in the precise dosages according to their individual requirements, during the appropriate time period, and with the necessary information for their correct use and in accordance with the law.

Minor Ailment Service

This is the Clinical Professional Pharmacy Service provided upon patient request when unsure of which medicine to acquire and when requesting the most appropriate remedy from the pharmacist for their specific health problem. If the service requires medicinal dispensing, this shall be carried out in accordance with the previous definition.

Medication Review with Follow-up Service

This is the Clinical Professional Pharmacy Service with the objective of detecting problems related with medicines (DRP), in order to prevent and resolve negative outcomes related to medicines (NOMs). This service requires a pharmacist commitment, and it should be conducted in a continual, systematic and documented manner, collaborating with the patient and other healthcare professionals, in order to attain specific results that will improve the patient's quality of life.

Medication Reconciliation Service

This is the Clinical Professional Pharmacy Service helps to identify, classify, evaluate and resolve possible discrepancies in pharmacological treatment generated in transit between levels of care in the health system.

The pharmacist's intervention in this service helps to prevent potential harm from the use of medicines. A critical objective in transitions of care, and especially at the time of hospital discharge, is the maintenance of patient safety.¹¹

Therapeutic Adherence Service

This is the Clinical Professional Pharmacy Service that includes both the behaviour of patients in relation to their pharmacological treatments as well as the adherence to hygienic-dietary recommendations or the adoption of lifestyle changes in patients.

The pharmacist, in collaboration with the patient and other healthcare professionals, can assess, identify and intervene on problems related to non-adherence in a protocolised and individualised manner.

Follow-up Episode

This is a one-time study of an occurring Incidence in the Dispensing Service, in which, using the methodology of the Medication review with follow-up Service, the aim is to identify the Drug-Related Problem (the cause and, therefore, the risk of a Negative Outcome Associated with Medications).

Incidence

It is any circumstance related to pharmacotherapy that, in the course of the established Dispensing procedure, is not consistent with an expected or accepted situation, and interrupts the procedure, forcing it to be evaluated in a Follow-up Episode.

Personalised Medicines Information (PMI)

This is the information provided by the pharmacist to the patient about their treatment, in the dispensing process, with the aim of achieving effective and safe use of the treatment.

Intervention

An action aimed at modifying certain characteristic of the treatment, the patient using the treatment, or the conditions of use, and which is intended to resolve a Medication Related Problems/Negative Outcomes Related to Medicines.

Drug Related Problems (DRP)

These are those situations that may cause the occurrence of a negative outcome associated with the medication (NOM). MRP are elements that may indicate an increased risk of the medication user's suffering from a NOM.

Negative Outcomes Related to Medicines (NOMs)

These are negative outcomes in the patient's health, not in line with the objectives of the pharmacotherapy, potentially associated with the use of medicines.

Medication discrepancy

We defined medication discrepancy as the difference between the list of medications in the medical record and what patients took after care transition.

- **Justified discrepancy (no clarification required):** discrepancy that is explained by the information contained in the discharge report or by the information obtained in the interview with the patient, or that requires clarification, and the prescriber does not modify the treatment once informed of it.
- **Discrepancy requiring clarification (unjustified):** discrepancy that cannot be explained, a priori, by the clinical situation of the patient thereby requiring a consultation with the doctor responsible for the patient.
- **Conciliation error:** discrepancy requiring clarification that is reported to the doctor and corrected in the prescription.
- **Discrepancy awaiting resolution:** discrepancy requiring clarification, yet the prescriber could not be contacted, or no response was received..

Community Healthcare Services

Those are activities carried out from the Community Pharmacy by a pharmacist who uses his or her professional competencies in health education, promotion and protection, as well as in disease prevention, using, where appropriate, the corresponding public health programmes and/or resources, in collaboration with all the agents involved.

Collaborative diagnostic support by the physician

These are those activities carried out from the Community Pharmacy through telematic means, by a pharmacist in collaboration with other health professionals, to verify the signs, symptoms or health history of a patient, with the aim of facilitating the diagnosis of a health problem.

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