Good Pharmacy Practice in Spanish Community Pharmacy

Medication Review with Follow-up Service in Community Pharmacy
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Introduction

In Spain, increased life expectancy, improvements in the healthcare system and in the treatments given, as well as the adoption of certain life styles have resulted in the predominant epidemiological profile being shaped by chronic diseases.

According to data from the National Statistics Institute (INE), on 1st January 2011 there were 8,092,853 people over the age of 64, or 17.2% of the total population. In 2009 this group already accounted for 16.6% of the patients insured by the National Healthcare System (SNS) and for 77.1% of the spending on medicines and medical devices\(^1\), in addition to generating other healthcare costs (hospital admissions, medical emergencies, etc.).

Current demographic trends would lead to a gradual reduction in population growth in coming decades, with the number of people older than 64 doubling in 40 years, comprising 31.9% of Spain’s total population by 2049\(^2\). This same trend is being observed in Europe and worldwide.

Medicines represent our most advanced technology for treating health problems. In Spain in 2013, Primary Healthcare public spending on medicines totaled 9.183 billion euros, an investment that requires methods to ensure a correct use that optimizes the health outcomes obtained and ensures the control of the health problems treated. Failures in effectiveness and safety are costly both to the health of the patients and to the economy. They result in hospital admissions or emergency visits, visits to doctors and additional pharmacological treatments and the costs these entail. Thus the morbidity and mortality rate associated with medicines poses a significant public healthcare problem, one that nowadays worries healthcare professionals and governments alike.

Pharmacists must share with doctors, other healthcare professionals, patients and healthcare authorities in the task of ensuring the safe, effective and efficient use of healthcare services and medicines. The concept of health, in its broadest sense, implies the full use of all healthcare resources, enhancing multidisciplinary healthcare teams (collaborative practice) and, in particular, coordinating doctors and pharmacists to increase the therapeutic benefit of medicines.

To this end, Spain has a specific professional service within the pharmaceutical care area, the Medication Review with Follow-Up Service (MRFU), which can help lower the morbidity and mortality associated with the use of medicines.

The Pharmaceutical Care in Community Pharmacy Forum (FORO AF-FC) defines this service as “the professional service having the goal of detecting problems related to medicinal products (DRP), for the prevention and resolution of negative outcomes associated with the medicine (NOM). This service requires considerable commitment and should be provided on a continual basis, in a systematized and documented manner, in collaboration with the patient and other healthcare professionals, in order to attain specific results that will improve the patient’s quality of life”\(^3\).

The pharmacist must be involved not only in preventing and resolving NOM when these appear, but also in comprehensively dealing with all of the patient’s health problems, in engaging in educational activities, in monitoring treatments and their effects and, in general, in doing any activity that can optimize the treatment of health problems and yield the greatest benefit possible of the pharmacotherapy used by the patient.

The MRFU, therefore, is a clinical activity that relies on using and measuring clinical variables (symptoms, signs, and clinical events, metabolic or physiological measurements) that can be used to determine if the pharmacotherapy is necessary, effective and/or safe.

This document contains the recommendations needed so that the MRFU Service can be regarded as a good professional practice.

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\(^1\) Information available at [http://www.ine.es](http://www.ine.es)

\(^2\) Long-term population outlook in Spain INE. 2012 Available at: [http://www.ine.es](http://www.ine.es)
Objectives of the Medication Review with Follow-up Service

The objectives of the MRFU Service are:

a) To detect DRP so as to prevent and resolve NOM.

b) To maximize the effectiveness and safety of treatments, minimizing the risks associated with using medicines so as to yield positive health results.

c) To contribute to the streamlining of medicines, improving the process for their use.

d) To improve the quality of life of patients.

e) To record and document professional interventions.

Procedures for the Medication Review with Follow-up Service

The MRFU Service involves a cyclical process whose basic outline is shown in Figure 1.
Overall, the MRFU Service tends to focus on three main aspects:

**Situation Analysis.** The pharmacist analyzes the patient's situation in terms of his/her health problems and medicines by drafting situation status reports and evaluating the pharmacotherapy.

**Action plan.** The pharmacist intervenes in conjunction with the patient to prevent, resolve or improve any faults in the pharmacotherapy in an effort to achieve the goals proposed for the patient.

**Evaluation and follow-up.** The pharmacist, in consensus with the patient, must periodically check whether or not the initially proposed goals have been reached.

The MRFU considers several phases (stages) that are detailed below:

1. **Service offer:** since the service is not widespread and is unknown to most patients, in practice the demand for it is low. This is why the pharmacist should offer the service to candidate patients, explaining to them the benefits of the service they are going to receive, what it is, what its goal is and what its key features are.

   This service is available to any patient who is on at least one medicine. There are groups of patients, however, who are eligible for more benefits. These include patients with a chronic disease like diabetes, high blood pressure and mental health problems, to cite a few. It can also be offered to groups of patients with specific characteristics, such as seniors (over 64) and/or polymedicated patients, those who use medicines with a narrow therapeutic window, are under special medical control or when referred by hospitals.

2. **Interview to gather basic data:** the pharmacist must follow a work procedure that allows him/her to gain full knowledge of a series of personal and health-related facts involving the patient. To this end, the community pharmacist will set up a series of personal interviews intended to generate a working relationship focused on the pharmacotherapy and on the health problems indicated by the patient so as to achieve optimal results or to intervene so as to correct the DRP or NOM detected or at risk of appearing.

   Once the patient decides to take part in the service, a first interview is set up, to which he/she is asked to take a bag with all of the medicines he/she is using or has at home. It is important to insist that he/she take every medicine, including those that patients sometimes do not regard as medicines, such as lotions or shampoos, homeopathy products, vitamins, etc.

   The first interview should last around half an hour, though this may vary significantly depending on the interviewer's skill or experience and on the complexity of the patient and the pharmacotherapy involved. Obviously this initial interview is the longest of the interviews that will be conducted over the course of the MRFU Service (subsequent interviews).
At the start of the interview the patient must sign a consent form, stating that:

- He/she is aware of the MRFU service.
- He/she can stop the service whenever he/she desires.
- He/she will provide updated and truthful information pertaining to his/her treatments, immediately informing the pharmacist of any changes to his/her medication and/or of any health problems.

The pharmacist will sign the same document, indicating his/her commitment to:

- Not use the patient's data without his/her consent, pursuant to the Organic Law on the Protection of Personal Data (LOPD).
- Adhere to the procedures and quality standards for the provision of the MRFU Service.
- Inform the doctor of any problem detected during the process that requires his/her involvement.

Once the authorization is signed by the pharmacist and patient (or his/her representative), a copy will be given to the latter, with another copy being kept in the pharmacy.

It is recommended that when providing the MRFU Service, a personalized care area be made available separate from the dispensing area so as to ensure the confidentiality of the interview and of the patient.

The data that the pharmacist must collect from the patient during the initial interview include:

- **Who** the patient is: personal and health information, background, any special physiological conditions.

- **What medicines** he/she uses or has used, including
  - The name of the medicine.
  - Who prescribed it.
  - The prescription/dispensation date.
  - The treatment start date.
  - The regimen prescribed and used by the patient.
  - Treatment type, sporadic or not, active or not.
  - Knowledge of the treatment (indications, etc.) and storage conditions of the medication.
  - Adherence to the treatment.
  - Treatment duration.

- **What diseases** have been diagnosed in the patient or what health problems he/she presents, as well as his/her concern with, knowledge and control of said diseases/problems.

- **Biological parameters** (analyses, anthropometric values, etc.).
3. Preparation of the situation status report: with the information gathered during the initial interview, the community pharmacist will draft a situation status report of the patient, listing each medicine and the diseases or health problems reported, taking into account other information like the biological parameters and any observations that the pharmacist deems convenient to note (possible allergies, body mass index (BMI), etc.). The situation status report is a document that summarizes the relationship between the patient’s health problems and the medicines on a given date. It is thus a tool that provides a “snapshot” of the patient’s health at a specific point in time.

<table>
<thead>
<tr>
<th>DATE:</th>
<th>NAME (No.):</th>
<th>GENDER:</th>
<th>AGE:</th>
<th>WEIGHT:</th>
<th>BMI:</th>
<th>Allergies:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>HEALTH PROBLEMS</th>
<th>MEDICINES</th>
<th>EVALUATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>Health problems</td>
<td>Controlled</td>
</tr>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td></td>
<td></td>
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<td>I</td>
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<tr>
<td>J</td>
<td></td>
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</table>

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<thead>
<tr>
<th>REMARKS:</th>
<th>PARAMETERS</th>
</tr>
</thead>
</table>

4. Study phase: intended to gain a deeper knowledge of the health problems and of the medicines used. The study phase makes it possible to evaluate and identify DRP\(^3\) and NOM\(^4\) or the risk of NOM (when the pharmacist identifies a DRP but there is no NOM, the risk that an NOM will appear exists).

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\(^3\) DRP: those situations that may cause the occurrence of a NOM. DRP are elements that may indicate an increased risk of the medication user’s suffering from a NOM. (Practical Guidelines for Pharmaceutical Services in Community Pharmacy, FORO AF-FC).

\(^4\) NRM: negative outcomes in the patient’s health not in line with the objectives of the pharmacotherapy, potentially associated with the use of medicines. (Practical Guidelines for Pharmaceutical Services in Community Pharmacy, FORO AF-FC).
The table below shows areas of inquiry during the MRFU study phase:

**Table 1. Aspects involved in the study phase**

<table>
<thead>
<tr>
<th>Need for information</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health problems:</strong></td>
<td><strong>Evaluate pharmacotherapy:</strong></td>
</tr>
<tr>
<td>– Definition</td>
<td>– Need</td>
</tr>
<tr>
<td>– Causes</td>
<td>– Effectiveness</td>
</tr>
<tr>
<td>– Control indicators of the health problem</td>
<td>– Safety</td>
</tr>
<tr>
<td>– Aggravating factors</td>
<td></td>
</tr>
<tr>
<td>– Criteria for referral to doctor</td>
<td></td>
</tr>
<tr>
<td>– Treatment (start, elective treatment, alternatives)</td>
<td></td>
</tr>
<tr>
<td><strong>Medicines:</strong></td>
<td><strong>Prepare action plan:</strong></td>
</tr>
<tr>
<td>– Indications</td>
<td>– Support decisions</td>
</tr>
<tr>
<td>– Pharmacological action and action mechanism</td>
<td>– Determine how to proceed</td>
</tr>
<tr>
<td>– Therapeutic goal</td>
<td>– Work with healthcare team</td>
</tr>
<tr>
<td>– Dosage and regimen</td>
<td></td>
</tr>
<tr>
<td>– Correct use and administration guidelines</td>
<td></td>
</tr>
<tr>
<td>– Adverse effects</td>
<td></td>
</tr>
<tr>
<td>– Aspects that could compromise the effectiveness and safety described previously in the available references.</td>
<td></td>
</tr>
<tr>
<td><strong>Educate patient:</strong></td>
<td></td>
</tr>
<tr>
<td>– Increase knowledge</td>
<td>– Increase knowledge</td>
</tr>
<tr>
<td>– Involve in decision-making</td>
<td>– Involve in decision-making</td>
</tr>
<tr>
<td>– Develop skills</td>
<td>– Develop skills</td>
</tr>
<tr>
<td>– Change attitudes</td>
<td>– Change attitudes</td>
</tr>
</tbody>
</table>

The pharmacist will need reference material with clinical guidelines, databases like BOT Plus 2.0, pharmacology and pathophysiology books, etc.

*Source: Sabater-Hernández D, Silva-Castro MM, Faus MJ. Dáder Method Medication Review with Follow-up Guidelines*
5. Evaluation phase: this stage involves properly identifying the possible DRP/NOM.

Classifying the DRP:

- Incorrect administration of the medicine.
- Personal characteristics.
- Inappropriate storage.
- Contra-indications.
- Inappropriate dosage, treatment and/or duration.
- Duplicities.
- Dispensing errors.
- Prescription errors.
- Non-adherence.
- Interactions.
- Unnecessary medicinal products.
- Other health problems affecting treatment.
- Probability of adverse effects.
- Other inadequately treated health problems.
- Others.

Clasificación de los RNM:

<table>
<thead>
<tr>
<th>NEED</th>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need for medicine (untreated health problem)</td>
<td>The patient suffers from a health problem associated with not receiving a medicine he/she needs.</td>
<td></td>
</tr>
<tr>
<td>No need for medicine (effect of an unnecessary medicine)</td>
<td>The patient suffers from a health problem associated with receiving a medicine he/she does not need.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EFFECTIVENESS</th>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-quantitative ineffectiveness</td>
<td>The patient suffers from a health problem associated with the non-quantitative ineffectiveness of the medication</td>
<td></td>
</tr>
<tr>
<td>Quantitative ineffectiveness</td>
<td>The patient suffers from a health problem associated with the quantitative ineffectiveness of the medication</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SAFETY</th>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-quantitative safety risk</td>
<td>The patient suffers from a health problem associated with the non-quantitative safety risk of the medicine</td>
<td></td>
</tr>
<tr>
<td>Quantitative safety risk</td>
<td>The patient suffers from a health problem associated with the quantitative safety risk of the medicine</td>
<td></td>
</tr>
</tbody>
</table>

The community pharmacist will discuss with the patient his/her concerns and establish an action plan (pharmaceutical intervention) It is important to remember that it is not the pharmacist who decides which problem to address first; rather, it is the result of a decision made in concert with the patient based on the “shared decision-making model”, in which the patient’s decision, and thus his/her specific concerns, are determining factors.
6. Pharmaceutical intervention (action plan): refers to any action whose goal is to resolve a DRP/NOM by modifying some characteristic of the treatment, of the patient using it, or the conditions of use of the medicine.

The pharmaceutical intervention can be carried out:

- Directly with the patient - for those situations that do not require modifying essential aspects of the pharmacotherapy. That is, only when changes in the patient’s behavior are required, for example, if he/she is not adhering to the treatment or if he/she does not understand aspects related to the use of the medicine (dose, regimen, duration, or storage conditions).
- In concert with the doctor (or other healthcare professional, as applicable) - when an essential aspect of the pharmacotherapy must be modified, such as adding or discontinuing a medicine, changing the dose or regimen, etc. In this case the corresponding doctor or healthcare professional must analyze the benefit/risk ratio of the treatment and make the pertinent changes. In these cases, communications can be handled through an interview with the doctor (by telephone or in person) or in writing (letter or e-mail).

The possible interventions proposed by FORO AF-FC are:

- Provide information (PTI).
- Offer healthcare education.
- Refer to doctor informing of DRP/NOM.
- Refer to doctor proposing treatment changes.
- Propose other modifications.
- Notify to pharmacovigilance systems in accordance with the applicable law (see Procedure on “Pharmacovigilance and activities to prevent the entry of counterfeit medications”).

7. Evaluating the results of the intervention: in this phase the community pharmacist evaluates the acceptance of the pharmaceutical intervention proposed on behalf of the patient either by the patient or his/her doctor.

Also evaluated are the changes in health observed (generally clinical results), though occasionally intangible results such as the patient’s satisfaction with the service or his/her perceived quality of life related to health (QLRH) can also be evaluated.

8. Record: as with all clinical practices, the MRFU must be documented. This is essential to the conduct of this service. The pharmacist must have proper documentation systems for recording this activity.

As with any professional involved in providing healthcare, pharmacists must comply with the clinical information and documentation requirements specified by law and with the responsibilities associated with the handling of the patient’s personal information.

The mere act of recording the various process indicators and results can demonstrate the effectiveness of the service.

In this regard, one of the most important points to realize is the need to compile the patient’s pharmacotherapy records, which will form part of a shared clinical history.

Once the results of the pharmaceutical intervention are analyzed, the pharmacist will record the findings of said intervention.

In subsequent interviews, the pharmacist will prepare a new situation status report and determine whether the various health problems remain under control or not (or have disappeared) and whether the DRP/NOM have been addressed or not.
Flowchart for the Medication Review with Follow-up Service

- Who is the patient
- Medicines taken
- Diseases/health problems reported
- Biological parameters
References


- Rodríguez-Chamorro MA, García-Jiménez E, Rodríguez-Chamorro A, Pérez Merino EM, Martínez-Martínez F. Adaptation of the situation status report to the Consensus Document defined by FORO. Ars Pharm 2011; 52 (suppl 1): 35-39.

