





Strategy to optimize patient safety in the community pharmacy dispensing service. Proposed checklists

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KEYWORDS

Checklist, Community Pharmacy, Controlled Release Formulations, Medication Errors, Orodispersible Tablets, Patient Safety, Community Pharmacy Services, Transdermal Patch

ABBREVIATIONS

ICU: Intensive Care Unit
MESH: Medical Subject Headings
MRF: Modified Release Formulae
MDS: Monitored Dosage System
PSWG: SEFAC Patient Safety Work Group
PTS: Pharmaceutical Treatment Services
SC: Surgical Checklist
SEFAC: Spanish Society of Clinical, Family and Community Pharmacy
SOP: Standard Operating Procedure
TTS: Transdermal Therapeutic Systems
WHO: World Health Organization

ABSTRACT

Dispensing is the most requested and important service within the tasks performed by the pharmacist, in his day-to-day work, in the community pharmacy. The aim of dispensing is to guarantee the patient's access to the medicine in an adequate and controlled manner. During that process, the community pharmacist has the obligation, as a healthcare professional, to actively participate in a committed manner in the detection of possible medication or medication-related errors.

SEFAC's patient safety group has developed, as the beginning of a series of future projects, checklists and best guidelines for medicines formulated as transdermal patches, modified release forms or orodispersible tablets.

The aim of this initiative is to minimize as far as possible, by means of a prior interview with the patient and the use of these tools, any errors or problems that might arise with these drugs, thereby ensuring patient safety.

A pilot project is expected to begin throughout 2023 in community pharmacies that collaborate with SEFAC's patient safety group. Therefore, they will be able to collect and report the results obtained.

INTRODUCTION

Patient safety is defined in accordance with the World Health Organization (WHO) as the health treatment discipline, whose aim is to prevent and reduce risks, errors and injuries suffered by patients during the provision of healthcare (1,2).

In accordance with incidence studies on medication errors made in a global setting, we can conclude that up to 80% of errors related to diagnosis, prescription and use of medicines could be prevented (3-5).

Similarly, if we focus on national terms, the estimated cost for the Spanish National Health System in accordance with the latest Spanish Ministry of Health document on the patient safety strategy 2015-2020, is approximately 1.8 billion euros, which represents almost 3% of Spanish Health System health expenditure (6).

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According to Spanish Law 29/2006 of 26 July, on guarantees and rational use of medicines, when dispensing pharmacists "will ensure compliance with the guidelines set out by the patient's attending physician for prescription, and cooperate with him during treatment follow-up by means of pharmaceutical treatment procedures, which contribute to ensure their efficacy and safety" (BOE-A-2006-13554). It is, therefore, the pharmacist's responsibility to contribute to the safety of medication (7).

The Council of Europe presented resolution CM/Res (2020) that enables health authorities from all over Europe to implement pharmaceutical treatment (8). The main aim of all health professionals involved in the medication process must be to improve the patient's quality of life. Therefore, collaboration between health professionals is essential to improve the population's health outcomes. Pharmacists can contribute to the integral control of pharmacotherapy in coordination with other health professionals. Among the activities to perform, by means of the process of pharmaceutical treatment, the detection of problems related to pharmacotherapy, such as contraindications, duplicates, prescription errors, interactions, etc. is notable (9). Community pharmacy is a safety filter to detect possible incidences and errors with medicines (3).

One way to attain better results in the field of patient safety might be setting up a Standardized Operating Procedure (SOP) with checklists for all processes in which an error might be made during the dispensing service.

Checklists as a safety tool originate from the world of aviation where verifying critical points before the aircraft takes off, serves to improve the trip's favourable prognosis. These checklists in the world of aviation, were designed to markedly reduce air mortality (10,11), which led to them being incorporated into the health system by the WHO in 2008. They reveal the critical points that must be considered in operating theatres under the maxim "Safe Surgery Saves Lives" on five different levels:

- Organizational.
- Checklist.
- Individual.
- Technique.
- Implementation.

The pilot studies on Checklists in Intensive Care Units (ICU) managed to reveal a marked statistical significance in mortality rates with a positive balance in terms of their usefulness by means of (10):

- Minimizing errors.
- Minimizing the risk of infections.
- Teamwork.

This positions checklists as a tool transposable to the field of primary care and community pharmacy. These are key aspects to favour quality and safe dispensing of the various pharmaceutical forms (12).

Checklists whilst dispensing medicines with complex pharmaceutical forms, with specific use and handling, may be a tool to optimize patient safety that can be explored (13).

After an exhaustive search, no publications were found on the use of checklists on transdermal patches, modified release forms and orodispersible tablets during the dispensing service in community pharmacy. Only publications in health services were found from a general point of view. Therefore, we have before us a pioneering initiative in the field of community pharmacy patient safety.

The Patient Safety Work Group (PSWG) of the Spanish Society of Clinical, Family and Community Pharmacy (SEFAC), comprised of 35 pharmacists, considered working on a safety project related to checklists during the dispensing of some complex pharmaceutical forms.

MATERIALS AND METHODS

The following strategy was used to conduct this project:

A team of 10 community pharmacists belonging to the cited work group was set up.

A brainstorming session took place to define the work topic. It was concluded that checklists would be prepared during dispensing of three complex pharmaceutical forms: transdermal patches, modified release forms and orodispersible forms. A bibliographical search was performed in PubMed, Google Scholar, Cochrane and Scielo using "Patient Safety" as a search term between January and November 2022.

A total of 35, 20, 11 and 125 papers were obtained in PubMed, Google Scholar, Cochrane and Scielo, respectively. Results were entered into the Zotero platform.

By means of a shared online document and a series of online Zoom meetings, a compendium of good practices was prepared for each pharmaceutical form (patches, modified release forms and orodispersible tablets), as well as a table with questions to pose during the dispensing service. Brainstorming initially took place, a bibliographic search was performed on the topics proposed and references were selected by the group's members. Subsequently, the PSWG coordinator was responsible for giving form to the document's content. This Checklist SOP aims to serve to optimize each community pharmacy's dispensing protocols on safety. Compendia were prepared using information compiled in the bibliographic search by means of preparing own and copyright-free images.

PROPOSED CHECKLISTS

The SEFAC PSWG has designed a series of infographics as a compendium and checklists to work with them during the dispensing service. This is to optimize provision of the pharmaceutical forms studied in the community pharmacy dispensing service. It is thus aimed to visually strengthen the key steps shown in the checklists during the dispensing of these pharmaceutical forms, which serve as support to the community pharmacist (14–16).

Moreover, to perform this project from the CP, the outline of the methodology proposed by Pharmaceutical Care Forum in Community Pharmacy (Foro AF-FC) and the practical guide for Pharmaceutical Services in the Community Pharmacy to perform the Dispensing Service will be followed (17).

"Therefore, the pharmacist, in the event of a request for a medicine and after systematically verifying that the applicant for dispensing is the patient or carer, and the latter have sufficient information for their effective and safe use, verifies with the available information that the medicine is suitable for this patient, complies with the prevailing regulations and dispenses or does not dispense, together with the necessary information for optimal use."

Transdermal patches (Appendix 1 and 2)

Transdermal therapeutic systems (TTS) or transdermal patches are pharmaceutical forms whose topical application enables dosing the medicines continuously transferred at a scheduled speed and for a set period of time, such that a systemic or specific action is obtained on a determined organ or system (18,19).

Advantages

- They are especially useful for long term treatments as they facilitate detailed posological monitoring, with a constant, sustained and controlled release of the active substances that comprise them. Therefore, it must be guaranteed that these systems favour release of the medicine through the skin up to the bloodstream (19,22).
- Transdermal patches enable administering a broad variety of medicines, such as those used in hormonal therapy and hormonal contraception, among others (23). New uses such as insulin transdermal patches for diabetes patients, which enable improving acceptance (reducing the stress caused by the injection itself) and safety during dosing (controlled insulin secretion by means of determining blood pH and considering weight and the sensitivity of insulin supplied by each patient); avoiding errors and adverse effects, are also being investigated (24,25).

Disadvantages

It is important to verify that the posological recommendation for the patch is correct, that the patient knows how to use it, in which areas to place it, how to throw it away and

ensure there is no incorrect use of the patch such as folding, cutting and/or using the same patch repeatedly (single use patch). Moreover, avoid direct exposure to sources of heat, which must be supervised during the patient's pharmacotherapeutic follow up (20,25).

Modified release forms (Appendix 3 and 4)

The administration of oral medicines (tablets, capsules, powders, suspensions and solutions) is the most common, ideal and preferred method of administration, because of its convenience and safety compared to other methods (26).

Modified release pharmaceutical forms (MRF) are those designed such that the speed or place of release of the active substance change according to the immediate release pharmaceutical forms of the active substance itself (27).

Advantages

MRF enable medicines with a short action duration to be administered less frequently, thereby favouring therapeutic compliance. They usually entail improved pharmacokinetics of the active substance with increased bioavailability and a better toxicological profile; minimizing gastrointestinal adverse effects. In the specific case of opioids, MRF also reduce the risk of developing addiction because of lowering the maximum concentrations of opioids and increasing the times these are attained compared to immediate release forms. All these advantages mean that MRF are especially interesting for chronic diseases, in medicines with strict therapeutic compliance to maintain plasma concentrations within the limits of effectiveness and toxicity; for medicines absorbed quickly, are short duration or those medicines broken down in an acidic environment (27,28).

Disadvantages

- Problems associated with incorrect handling. MRF usually present in the form of tablets or capsules that must not be administered chewed or crushed because of their potential toxicity and loss of long term effect. The patient should be warned that in general MRF should be swallowed whole. In the specific case of opioids, oral prolonged release pharmaceutical forms are highly susceptible to being altered as they contain a higher amount of active drug than immediate release formulations. Moreover, oral prolonged release pharmaceutical forms are much easier to handle than other pharmaceutical forms, such as transdermal patches. Exceptionally, some modified release tablets have a break groove and can be split. Some capsules of this kind contain microgranules, which enable them to be directly administered by tube or mixed with food if their integrity is maintained. There are no general rules and in each case the possibility of handling the medicine safely must be confirmed with the manufacturer and technical specification. The information on the possibility of splitting or crushing capsules or tablets

is covered in the technical specifications and prospectus for the medicine (26-29).

- Exacerbation of overdose or onset of adverse reactions as a consequence of the prolonged action of medicines formulated as MRF.
- Pharmacological interactions with foods. Foods can alter the release of a medicine formulated as MRF.

Orodispersibles (Appendix 5 and 6)

Orodispersible tablets according to the Spanish Royal Pharmacopoeia are non-coated tablets aimed to be placed in the mouth, where they quickly disperse before being swallowed. They are characterized because they must be broken down in less than three minutes when subjected to the general breakdown test for tablets and capsules; that is, at a temperature 35°C – 39°C, in a liquid medium and in a tablet divider that complies with specifications (30).

Advantages (29-31)

- They combine the advantages of liquid forms and oral solid forms: they are accurate to dose and easy to swallow.
- They usually have a pleasant taste.
- The tablet does not need to be swallowed whole or with water as it dissolves quickly in saliva (1 to 3 minutes). This is especially an advantage for children, the elderly, Parkinson disease patients, people with dysphagia, phagophobia, mental disability and even patients treated with anti-psychotics.
- Improved bioavailability.

Disadvantages (30-33)

- They are more fragile. Due to the greater porosity they usually present that facilitates absorption of water inside, they lack the mechanical resistance of traditional tablets. Therefore, they are more susceptible to breakage.
- Excess humidity in the environment can lead to their physical instability.
- They cannot be incorporated into Monitored Dosage System (MDS).
- As they are a more novel pharmaceutical form, there is little knowledge by patients when they start to dissolve in the mouth.
- They are not recommended for patients with a lack of salivation as is the case in Sjögren syndrome, xerostomy and patients in treatment with anti-cholinergic medicines. These problems might be resolved to a certain extent by means of drinking a glass of water prior to taking the tablet.

APPLICABILITY

From the PSWG, a pilot study was performed in 20 pharmacies from different Autonomous Communities during 2023 (34). This enabled validating the applicability of these tools

in the form of protocols. The ultimate aim is to attain optimal patient safety standards that can be simply and effectively applied from community pharmacy.

It is aimed that the detection, reduction and resolution of errors that might impact the patient's safety reduce the associated health problems and rates of hospitalization and morbi-mortality because of medication errors.

In parallel, it is deemed appropriate to have a community pharmacist-general practitioner channel of communication to notify relevant points on patient safety that may arise during application of the SOP to checklists during the dispensing service.

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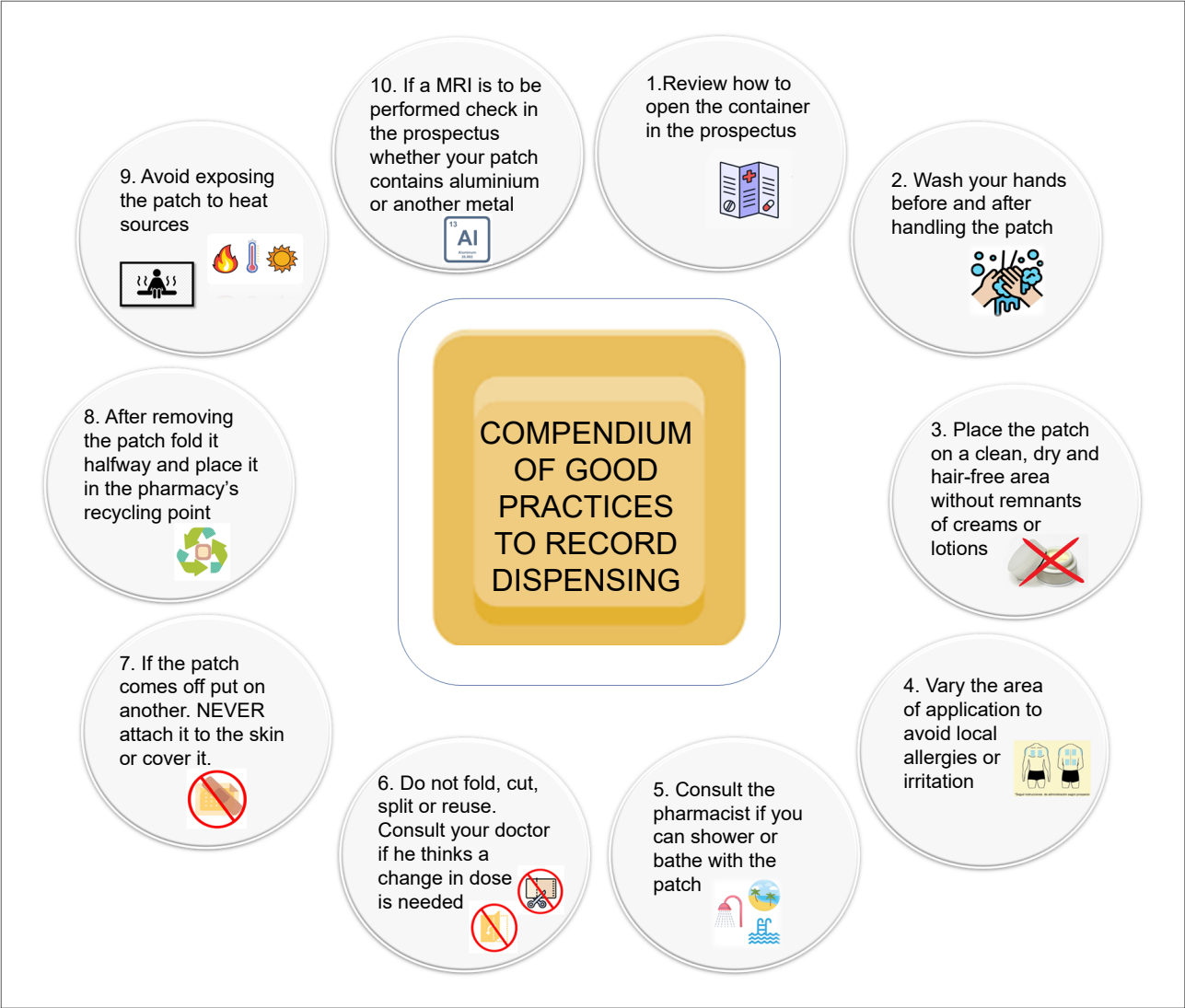
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Appendix 1 Compendium of good practices to record the dispensing of transdermal patches



[RETURN](#)

Appendix 2 Checklist during the dispensing service for transdermal patches

CHECKLIST DURING THE DISPENSING SERVICE		
Questions at initial dispensing	YES	NO
Is it the first time you are using transdermal patches?		
Has it been explained to you how to use them?		
Do you know the correct way to apply transdermal patches?		
Have you been told in which areas you can apply the patch?		
Do you know how long before you have to change it?		
Do you know what to do with the patch once it has been removed to put on another one?		
Questions at secondary or successive dispensing	YES	NO
Do you present irritation, dermatitis, erythema or discomfort in the area of application of the patch after its use?		
Is it a limitation for you to use the patch at those times of the year in which it may be visible for aesthetic reasons e.g. during summer?		
Is it comfortable for you to use the patch daily?		
Is it uncomfortable for you to use the patch in certain circumstances such as sports, showering, swimming or at the beach?		
Do you put the patch on at the same time each day?		
Do you have any difficulty when putting on/removing the patch?		
Do you usually forget to put the patch on? Has this ever happened?		
Do you usually forget to remove the patch. Has this ever happened?		
Questions on suitable use	YES	NO
Do you use the patch if it is damaged?		
Do you use it in an area covered by clothing?		
Do you place it in a hair-free, clean area without creams?		
Do you place it somewhere else other than the elbows, hands or knees?		
Do you change the patch as indicated by your doctor, pharmacist and/or as indicated in the prospectus?		
Do you change body area each time you use a new patch?		
Do you know what to do in the event the patch comes off?		
Do you know what to do if you see the patch has not been changed?		
Do you know what to do if you have been given a patch before removing the previous one?		

◀ RETURN

Appendix 3 Compendium of good practices to record the dispensing of modified release forms



◀ RETURN

Appendix 4 Checklist during the modified release forms dispensing service

CHECKLIST DURING THE DISPENSING SERVICE		
Questions at initial dispensing	YES	NO
Is this the first time you are taking the medicine?		
Do you know the correct way to administer the medicine?		
Has it been explained to you how to take it?		
Do you have any swallowing problem or any other discomfort that prevents you taking the medicine whole?		
Questions at secondary or successive dispensing	YES	NO
In the event this medicine has been replaced by one that is not modified release is this more comfortable on a daily basis?		
Do you observe at any time a reduction in the effect or do you believe it does not have the entire sought after effect?		
Have you had any difficulty taking the medicine?		
Questions on suitable use	YES	NO
Do you take the tablets or capsules whole, with enough water, without chewing, crushing or splitting?		
Do you know that in the event of problems swallowing you should talk to your doctor so she can evaluate a change in pharmaceutical form?		

◀ RETURN

Appendix 5 Compendium of good practices to record the dispensing of orodispersible tablets

<p>1. Read the medicine's prospectus in case there is any specific instruction</p> 	<p>2. Wash your hands before handling the tablets</p> 	<p>3. Dry your hands</p> 	<p>4. Separate one of the blister pack columns along the perforated lines</p> 	<p>5. Open the blister pack column starting in the corner shown by the arrow</p> 
<p>6. Do not pressure the orodispersible tablet to avoid it being crushed</p> 	<p>7. Take the tablet and put it on your tongue</p> 	<p>8. The tablet disintegrates quickly with your saliva</p> 	<p>9. There is no need to drink water or another liquid subsequently</p> 	<p>10. Do not keep tablets or capsules in places with humidity or temperature changes (kitchen, bathroom)</p> 

[◀ RETURN](#)

Appendix 6 Checklist during the dispensing of orodispersible tablets

CHECKLIST DURING THE DISPENSING SERVICE		
Questions at initial dispensing	YES	NO
Is this the first time you are taking the medicine?		
Has it been explained to you how to take it?		
Do you know that it dissolves on the tongue in a few seconds?		
Do you have any problems with dryness of the mouth?		
Do you know you must not store the medicine in the kitchen, bathroom or places where there are changes in temperature and humidity?		
Do you know it must not be dissolved in a glass of water?		
Questions at secondary or successive dispensing	YES	NO
Do you wait long enough for the tablet to dissolve of its own accord on your tongue?		
Did you stop taking it because you thought the taste was unpleasant?		
In the event you use a PDS, have you forgotten a dose because it is not kept with the rest of your medication?		
Do you take the medicine at the same time every day?		
Questions on suitable use	YES	NO
Is this pharmaceutical form more comfortable than others?		
Is it easy to take this medicine?		
Is it complicated to correctly extract the medicine from the blister pack?		
Does the tablet break when you take it out?		

◀ RETURN