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Antonella Valeria Penati *Editor*

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

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Antonella Valeria Penati
Editor

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

Editor
Antonella Valeria Penati
Department of Design
Politecnico di Milano
Milan, Italy

ISSN 2198-7300 ISSN 2198-7319 (electronic)
Research for Development
ISBN 978-3-031-53293-1 ISBN 978-3-031-53294-8 (eBook)
https://doi.org/10.1007/978-3-031-53294-8

Politecnico di Milano

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

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Chapter 8
Dispensing Medicines: A Necessary Link Between Doctor and Patient

Antonella Valeria Penati

Abstract Based on a broad body of literature, the chapter highlights the plethora of problems surrounding dispensing. These include the information gaps that punctuate the transition between prescription and dispensation, the inadequacy of the documentary supports (medical prescription, therapeutic plan, the patient's pharmacological history, information on current therapies, etc.), a not always transparent allocation of information tasks concerning the medical doctor and the pharmacist. The main insights that have oriented the research on the dispensary context are also presented: the focus on environmental requirements (organisation of space; logistics of pharmaceutical products; lighting, ambient noise), the emphasis on work organisation requirements (allocation of tasks to staff; task overload; task diversification), and the focus on the transformation of the pharmacy's nature from a place for dispensing medicines to a place for selling para pharmaceutical products and providing service). In particular, the chapter focuses on the limitations and problems associated with the prescription and packaging of medicine because of their importance in the dispensing phase.

8.1 Between Prescription and Dispensation: No Man's Land

> The prescription of a medicine constitutes the final act in the diagnostic process. It is one of the prerogatives and responsibilities of the medical doctor, who "has autonomy in the planning, choice and application of every […] therapeutic aid. […] The doctor is required to have adequate knowledge of the nature and effects of drugs, their indications, contraindications, interactions, and foreseeable individual reactions, as well as the characteristics of the use of […] therapeutic means […]" (the Italian Code of Medical Deontology, art. 12, pp. 10–12)
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> The dispensing of medicine "is a medical act to protect the health and psychophysical integrity of the patient. […] It is the exclusive prerogative of the pharmacist who is required to ensure adherence to pharmacological therapies, contributing to a higher level of effectiveness

A. V. Penati (✉)
Department of Design, Politecnico di Milano, Milan, Italy
e-mail: antonella.penati@polimi.it

A. V. Penati (ed.), *In-Home Medication*, Research for Development,
https://doi.org/10.1007/978-3-031-53294-8_8

> of treatment. […] The pharmacist's responsible for "rejecting applications for medicines without the prescribed medical prescription […] or made on prescriptions that do not meet the requirements established by law. […] except in cases of urgency […]. The dispensing of prescription medicines is subject to verification by the pharmacist of the formal and substantive requirements of the prescription to guarantee the protection of the patient's health. […] If necessary, the pharmacist […] shall, before dispensing the medicine, contact the doctor […] for the necessary clarification. The dispensing activity is not only a technical activity but also an activity of professional advice and counselling. In fact, the pharmacist is obliged to "provide clear, correct and complete health information, with particular reference to the appropriate use of medicines, their contraindications and interactions, side effects and their storage" (the Italian Pharmacists' Code of Ethics, 2018, Articles 8; 12; 13; 15).

A reading in sequence of the Italian Code of Medical Deontology and the Italian Pharmacists' Code of Ethics, giving each of the actors involved a specific role, seems to recompose the various stages necessary to make the medicine available to the patient, within a unitary process, guaranteeing its safe and informed use.

And yet, the process that theoretically seems seamless presents, as widely documented in the literature, several 'gaps' and critical situations. These gaps arise above all from a lack of communication and inadequate transmission of information between actors in the system: the pharmaceutical industry, the specialist or hospital doctor, the general practitioner, the pharmacist, and the patient. Despite robust legislation, communication connection tools are scarce.

The dialogue between doctor and patient is partly verbal and partly rendered in documents such as:

- the Medical Record or the Letter of Discharge (after a hospitalisation) showing the treatment carried out, the diagnosis, the therapy carried out at home, the dosage and, not infrequently, during and after the treatment, diagnostic exams necessary to detect values that the therapy might alter;
- the report for the general practitioner (after a specialist examination), giving the diagnosis, therapy, dosage and, not infrequently, during and after treatment, diagnostic exams necessary to detect values that the therapy might alter;
- a brief note, not always present (after a general practitioner's visit), to remind the patient of the dosage of the prescribed medicines;
- the prescription, which acts as a 'witness' in the passage of information between doctor and pharmacist. It is not intended for the patient, who merely transfers the prescription from the prescriber to the dispenser.

As sources of information, the patient has:

- the Package Leaflet, arriving in the patient's hands together with the medicine and formulated to address the doctor, the pharmacist, and the patient simultaneously. Actors with very different information needs;
- the secondary packaging of the medicine, guiding the selection of the medicine at the time of dispensing, with its information apparatus.

A study conducted in Northern Europe on the information needs shown by patients concerning therapies finds that, in addition to the doctor (in first place) and the pharmacist (in third place), the patient reads the package leaflet (in second place) to

supplement the information needed to follow the therapy correctly (Mamena et al. 2015). In assessing this attitude towards information, it must be considered that not all patients feel they can turn to the pharmacist for information on how best to manage their therapy.

An observational study based on the transcription of 189 outpatient encounters followed by interviews and carried out 1 week after the visit, found that 49% of the recommendations made by the physicians were remembered accurately without being prompted by the interviewer; 36% were remembered with prompting; 15% were remembered incorrectly or not at all. These percentages decrease significantly if the patient's schooling is low (Barton Laws et al. 2018).

A further study showed that the shortening of hospital stays and the trend towards outpatient care have increased patients' need for specific information even though, as the results of the study show, patients can remember very little of the information they received from the doctor (Kessels 2003). Contributing to this poor result are the patient's memory, the patient's ability to understand the information given by the doctor, whether the information is written down or transmitted verbally, the patient's instruction, and the doctor's use of medical jargon. The study rates the immediate removal of the information supplied by health professionals at between 40% and 80%. It also notes that the greater the amount of information presented, the lower the percentage of remembered correctly. About 50% consists of erroneous or faulty recollections of the information received (Kessels 2003). The lack of a document with a predefined format to help the doctor and pharmacist in giving directions to the patient and the patient in having the information available in a neat and searchable way over time, probably contributes to this.

When the patient comes to the pharmacy for medicine dispensing, pharmacists have the prescription as the only formal information at their disposal. They do not necessarily know the patient to whom they are dispensing the medicine—their medical and pharmacological history. In the case of first-hand familiarity with the patient, they may base their judgement on information 'reported' by the patient or—as we shall see—by tracing back through the laptop to previous medicines purchased from the pharmacy. In both cases, these are unreliable sources.

In this context, to build up an overall picture of helpful information for correctly managing the therapy, the patient must autonomously collect and reconstruct the elements provided fragmentarily by medical documentation, information dispensed by the doctor and pharmacist, and information on the package leaflet.

Information gaps are at the root of the many errors and problems at the dispensing stage.

8.2 Errors in Dispensing

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) from the United States defines medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medica-

> tion is in the control of the health-care professional, patient or consumer (Martìnez Sànchez 2013, p. 185)

The chapter stems from the analysis and comparison of the extensive international literature on errors in the dispensing phase and, more generally, on the problems connected with this activity.

The aim is to return the errors most frequently observed when analysing the dispensing activity, the phases in which they occur, and the possible causes, to build a reference framework for the definition of recommendations and design interventions to mitigate errors and encourage better communication between doctor, pharmacist, and patient. As we have already mentioned, many of the errors complained of in the literature originate precisely from the lack of tools to facilitate information exchange between the system's actors (Cohen 1999).

Even though our reflections are based on quantitative data, they avoid referring to statistical data and the formulation of error 'rankings'. This is because, when comparing different studies, it is necessary to address a few methodological issues for the comparison to be rigorous and the data to be meaningful. But also, because errors in healthcare—focusing on medicine dispensing activities—are worthy of attention, because these are common errors that can lead to high morbidity and even fatal outcomes. We refer to the sources analysed in more detail regarding percentage data and refer to the tables in Sect. 8.2 of this book for error statistics. In the following, we will devote ourselves to reconstructing an organic picture of the problems relating to dispensing medicine for the critical aspects detectable in this activity. Due to the point of observation assumed in this book, we will focus on errors that may arise from the doctor's prescription and the medicine's secondary packaging while attempting to give a broad overview of the criticalities of the dispensing moment.

Concerning the comparability of data from different studies, we are interested here to note that, while there is large-scale research relating to errors in the dispensing of medicines in hospital settings, it is more difficult to find a systematic study of a similar nature concerning dispensing in territorial pharmacies (Flynn et al. 2002; Hoxsie et al. 2006; Franklin and O'Grady 2007; Aldhwaihi et al. 2016).

This shortcoming emerges in the literature where it is difficult to find comparable outcomes, lacking a shared approach. The results of the different sources are not easily integrated or recomposable, depending on the research methods, the starting operational definitions, the context of analysis, the delivery system, and the errors' classification criteria (James et al. 2009). Below is a list, as exhaustive as possible, of elements and criteria to be considered to construct the correct premises for making the collected data comparable:

Typological-dimensional characteristics

- Public or municipal pharmacies;
- Private pharmacies;
- Community pharmacies/service pharmacies;
- National single-brand pharmacy chains;
- International single-brand pharmacy chains;

- Online pharmacies;
- Large retailers (for non-prescription medicines);
- Size of the pharmacy concerning the territorial basin served;
- Number and qualification of staff in the pharmacies surveyed.

Methods and size of the survey

- Database consultation;
- Bibliographic collections;
- Direct observation;
- Questionnaires;
- Online questionnaires;
- Interviews;
- Recording of interviews between pharmacists and patients during dispensing activities;
- Recording of pharmacist's thoughts aloud during dispensing;
- Duration of the recording;
- Day of the week;
- Seasonality of the survey;
- Size of the sample of pharmacies involved in the research;
- Peculiarities of the health cultures and regulations on prescribing/dispensing in the different countries.

Research objectives/definition of error

- Objectives of quantitative/qualitative data collection;
- Aims of the observational study;
- Purposes of the data collected;
- Diversity or absence of the definition of error underlying the research.

Presence/absence in the research of peculiar discriminants

- Dispensing of over-the-counter drugs/prescription drugs;
- Repeat prescription/Original prescription;
- Pharmaceutical form;
- Prescriptions made with digital/paper instruments;
- Manual dispensing/Semi-automated dispensing/Automated dispensing;
- Original pack dispensing or Compliance pack;
- Dispensing to regular/occasional patients;
- Dispensing to special categories of patients: infants, children, adolescents, elderly;
- Dispensing to patient/caregiver.

In addition to this long list of issues that can have a significant impact on the collected data, the reluctance to expose the error in the presence of a punitive mentality (Franklin and O'Grady 2007) and in the absence of a culture of problem-sharing that would help to redesign management and logistical activities, physical and digital infrastructures, the drug itself, the prescription and in general the objects that

support all the activities that precede the purchase of the drug by the patient. This reticence is a non-secondary factor that contributes to distorting the quantitative data.

To conclude, it is helpful to point out that comparing data on errors at the prescribing and dispensing stage problematic is the unambiguous definition of this type of error, which is sometimes not even prefixed to the study. Based on the comparison of numerous studies on errors in the prescribing and dispensing phases, one research report has revealed differences, even marked ones, between the definitions used (Aldhwaihi et al. 2016), just as distant are the positions in determining whether specific types of events are to be considered errors (Dean et al. 2000). These different positions influence the methods of detection and data collected. For example, concerning prescribing errors, some authors have defined errors as only those recognised by the doctor and the pharmacist. Other studies have included only those that harm the patient in this type of error. Some authors believe that insufficient patient education on the correct use and effects of the medicine should be considered among prescribing errors, giving less importance to bureaucratic-regulatory errors. Other authors, on the other hand, consider the prescription of a medicine by its brand name (instead of its active ingredient) to be one of the errors, namely a type of error that has no implications for the patient's health but contravenes the regulations in force. A similar variety is found in the definition of dispensing errors where, for example, a distinction is introduced between a dispensing error and a near-error, defining by this second term those errors made during dispensing but detected by the pharmacist before the patient left the pharmacy.

8.2.1 Prescription Errors Detected During Dispensing

The first group of errors, widely reported in the literature, consists of those made by the doctor at the prescribing stage. In many cases, the pharmacist detects these errors during dispensing procedures, highlighting a frequent recurrence: the error is not recognised by the person committing it but by those asked to take follow-up action at a later stage (Ferguson et al. 2018).

In this chapter devoted to medicine dispensing, we focus on prescriptive errors limited to those circumstances that allow us to highlight and give meaning to the close interconnections between the different stages preceding the patient's purchase of the medicine. The aim is to delineate the decision-making and management processes, the responsibilities, as well as the information passages and communication exchanges that take place between the different actors in the care system. Our attention lies particularly on verifying the effectiveness of the more traditional tools (paper prescriptions) or the more innovative ones (e-prescribing) in supporting this process and allowing effective and exhaustive communication between doctor, pharmacist, and patient.

Regarding the definition of prescriptive error, we adopt the one proposed by Dean et al. (2000). It emerges from an interdisciplinary group composed of

healthcare professionals, clinicians, pharmacologists, and researchers with extensive experience in medication error.

> A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice (Dean et al. 2000, p. 234).

This definition simplifies the framing of prescribing errors detected at the dispensing stage, by directing our attention to the distinction between errors in the prescribing decision and errors in the prescription writing process. This second category also includes errors occurring in the re-writing of therapeutic indications.

The first type refers to errors in medical decision-making: prescriptions that are contraindicated or inappropriate because they do not take into account the patient's overall clinical condition; prescriptions of medicines to which the patient has reported a clinically significant allergy; prescriptions of medicines that do not take into account interactions with other active ingredients in the patient's therapy; prescriptions of medicines in dosages that are inappropriate for the patient; prescriptions of "refills" of a medicine that has given the patient adverse reactions; prescriptions of "refills" of medicine without having carried out the required diagnostic investigations; prescriptions of two different medicines (or two medicines containing the same active ingredient) for the same indication for use; prescriptions of medicines for which there is no indication for the patient's condition, etc. (Dean et al. 2000).

Errors of 'writing', namely errors that occur in the coding phase of the clinical decision and its transposition onto a technical device—the prescription—aimed at translating the therapy into standardised data, include: the failure to communicate or the incorrect communication of information that is essential for correct dispensing (such as the exact, complete and legible name of the medicine; the pharmaceutical form; the dosage—especially in medicines available in several dosages—, the correct unit of measurement, the route of administration). These errors also include omitting the date, the patient's name, and the prescriber's signature.

Writing errors also include 'transcription' errors. These refer to the reading and re-writing of prescriptions previously made by the same doctor or other doctors (e.g., transcriptions by a general practitioner of prescriptions given by a specialist or a hospital doctor). The same type of error can occur when the hospital staff transcribes the patient's home treatment at the start of a hospital stay. This includes transcription automatisms typical of chronic therapies in which a medicine may be renewed without checking for changes (e.g., change of molecule, frequent in chronic therapies, or dosage changes). Finally, all those written directly on a prescription but not formally transcribed in the medical record or the doctor's computer system may give rise to subsequent errors. Failure to transcribe formally may lead to forgetfulness in subsequent prescriptions.

We refer to the tables by Dean et al. (2000, pp. 234 and 235) for an accurate list of the many prescription errors that affect the dispensing act. From the study of these authors, we limit ourselves here to identifying three categories of errors, with different implications on dispensing:

- prescribing errors/problems arising from the decision-making process, namely the clinical decision leading to the prescription;
- errors in prescription writing;
- errors in re-writing.

Each type of error could interfere with correctly dispensing the prescribed medicine. Still, it changes the pharmacist's ability to detect the error and even more so to intervene to correct the error found.

The first type of error—error as the outcome of a clinical decision—is strongly affected by the sharp caesura, established by law, between the activity of the prescriber and that of the dispenser, namely between the activity proper to the doctor and the clinical discretion and expertise, and the activity of health education, control and support of pharmacological treatment that is proper to the pharmacist.

In the absence of a formal passage of information informing the pharmacist of the reasons behind the prescription of a specific active ingredient and the choice of dosage, it is difficult for the dispenser to understand whether the choice made by the doctor is well-considered and intentional, even if outside the guidelines, or the result of an error. Similar doubts may arise from prescriptions potentially harmful to a patient undergoing polypharmacy due to the risk of medicine interactions or adverse reactions related to other diseases the patient is suffering from.

The pharmacist does not always understand the prescriptive decisions of the doctor. But, even when faced with doubts, it is difficult for the pharmacists to intervene: they have no documentation on the diagnostic part. Moreover, the doctor is not obligated to provide information in the prescription to explain the therapeutic choice.

The doubts raised by the doctor's clinical decision make even more sense in the case of prescriptions written by specialist doctors who, especially at the 'first visit', do not know the patient's medical history in depth and must rely on the clinical documentation and the problems 'referred' by the patients themselves. In particular, the therapy has no codified format and is not validated by the general practitioner. When introducing a new medicine into the therapy, the specialist relies on the patient's ability to return therapeutic data in the most complete and correct form possible. For instance, in the elderly patient, these are numerous and complex to return.

The second type of prescriptive error—namely the error occurring in the writing phase is generally caused by forgetfulness, distraction, and haste, leading the physician to write something different from the clinical intention/decision (for a detailed restitution of these different problems we refer to Table 1 of Chen et al. 2005, p. 337).

Even in this case, the literature is rich. It essentially comprises two forms of error: those that result from omitting information necessary to make the object dispensed unambiguous, and those that result from making unintentional errors in filling in the format with the required prescriptive data. In addition, the doctor's incomprehensible handwriting can be equated with an omission of data or lead the dispenser to an interpretative error (Martìnez Sànchez 2013).

Errors at the writing stage (due to absence or inconsistency of information) have been classified as errors of omission or commission. Errors of omission include 'incomplete prescriptions', while errors of commission include uncorrected, illegible prescriptions and indications given through abbreviations or acronyms (Al-Khani et al. 2014) or relating to products no longer available or for hospital use.

These types of errors require proactive intervention by pharmacists to correct them. Differentiating errors of omission (incomplete prescriptions) from unintentional errors of data and information helps highlight the different degrees of risk involved in dispensing. An omission is an evident error and is less likely to cause harm than errors resulting from erroneous data that are not always explicitly apparent and, precisely for this reason, can also be very dangerous. In other words, the absence of a data element that does not allow the identification of the medicine or the patient to whom the treatment is dispensed, produces the suspension of administering until the missing data have been completed. This type of error, unless a medical condition requires immediate administration of the medicine, delays dispensing. In contrast, incorrect medicine entry, such as writing *Metotrexate sodium salt 7.5 mg* 'per day' instead of 'per week' for a patient with rheumatoid arthritis, can lead to severe dispensing errors. This kind of error cannot necessarily be detected by the pharmacist thanks to the prescription because the doctor does not have to justify the treatment concerning the pathology.

The macro-category of writing errors (omission of data and incorrectness of the data entered in the prescription) has given rise to a research interest aimed at verifying to what extent digital prescribing (in use in many countries, and which has also become widespread in Italy, following the Covid-19 pandemic) can mitigate errors. We can here briefly argue that e-prescribing makes it possible to have prescriptions with fewer data gaps, but, at the same time, it produces contradictory results on the error relating to the data entered. Causes of medication errors (Martìnez Sànchez 2013, table 2, p. 185):

- Prescription corrections;
- Illegible prescription (illegible handwriting);
- Prescription of a non-existent medicine, strength, quantity or dosage;
- Missing prescriber information;
- Absent indication of the route of administration;
- Problems with subsidies;
- Medicine no longer in stock;
- Patient wanted to change prescription;
- Medicine not immediately available;
- Prescription is incomplete concerning dose or frequency;
- Medicine is indicated but dose is inappropriate;
- Missing or incorrect patient identification;
- Problems with medicine substitution;
- Medicine duplication.

The list above highlights that any data can be subject to problems of:

- illegibility or distortion of the medicine name;
- illegibility, absence or mistake in the dosage;
- illegibility, lack, or mistake in the number of doses per package;
- illegibility, lack, or mistake of the pharmaceutical form;
- illegibility, or lack of the prescriber's signature;
- illegibility, or lack of name/prescriber's registration number;
- illegibility, or lack of the patient's name.

The third typology refers to the distortion of data that can take place in the rewriting and transcription phase and can be due to causes such as the fast or incomplete reading of the original document; the misinterpretation of some data of the original document; the recombination, in the transcription, of characteristics related to different medicines present in the original prescription; the confusion between dosage and time of intake due to the absence of punctuation that makes the interpretation unambiguous, etc. (for a completeness of examples see Chen et al. 2005).

Suppose a comparison with the source document does not immediately detect them. In that case, the peculiarity of transposition errors is that they risk not remaining occasional but instead setting the tone for subsequent treatment.

The risk of transcription errors is particularly critical in phases of 'therapeutic discontinuity': hospital admission or discharge, specialist visits, and so forth, when new medicines are introduced, substituted, or eliminated.

Frequent transcription errors include those that occur in printing labels or instructions for use that the pharmacist affixes to the packaging prepared by the pharmacist. This type of error can lead to the provision of information that differs from the prescription and/or content (Hoxsie et al. 2006). This type of error refers to those countries where the drug is dosed and packaged by the pharmacist according to the doctor's prescription.

In this review of prescriptive errors that the pharmacist can detect, the literature also includes problems arising from the intrinsic risk of medicine therapy (e.g., side effects, medicine interactions, allergies) and those related to the process of medicine supply and reimbursement. Of these error types, the relevance to the dispensation phase is considered here because, if not recognised and reported, they may recur in subsequent prescriptions.

The literature testifies the presence of prescribing errors on the doctor's side. It rarely depends on a lack of knowledge of the patient's condition and pathology but, by contrast, on a knowledge of the medicines not always appropriate (e.g., side effects, drug interactions, drug manipulability, dosages, pharmaceutical forms available on the market, formal characteristics, and use of the drug). From this knowledge, which is not always adequate, may also depend on 'double prescriptions'. For example, a new medicine whose active ingredient is already present in the patient's therapy under a trade name not recognised by the doctor. Similarly, lack of appropriate knowledge of the shape, size, and surface characteristics (e.g., smooth or rough) of a tablet may lead the doctor to prescribe to elderly or dysphagic patients drugs that they are unable to swallow. The introduction of the legal obligation to place on the market packages equipped with an anti-tampering seal (Directive 62/EU 2011)

does not allow the user to know, prior to purchase, the formal characteristics of the medicine and, to date, there is no 'abacus of forms' to help the doctor, pharmacist, and patient in the choice of the medicine, also assessing its formal characteristics. Some of these prescriptive criticalities could be detected at the dispensing stage. But, as we shall see below, in many cases the pharmacist lacks the information, procedures and prerogatives to be able to intervene on behalf of the patient.

8.2.2 Dispensing Errors: Definition

The activity of dispensing a medicine does not end with checking the prescription and the correctness of its information content. As we have seen, verifying prescription data is a fundamental step. But it is not the only one. Dispensing is a complex process consisting of several operations: receipt of the prescription, reading, verification of completeness, interpretation, selection of the prescribed product, removal of the pharmaceutical sticker from the drug packet and its affixing to the doctor's prescription, registration of the dispensing using a numerical code, instructions and advice to the patient, release of the prescribed drug and registration of the sale using a receipt (Weir et al. 2020).

Medicine dispensing consists of a multistage process of technical checks and procedures, operational and organisational activities, mental processes, and dialogical and relational exchanges (James et al. 2009).

Each step in this process is intrinsically linked to the possibility of error. Although there has been increasing research on dispensing errors in recent years, there is no universally accepted taxonomy. One of the most frequently used definitions is the one elaborated by Flynn and Barker in 1999 and subsequently taken up by several authors (Flynn et al. 2002; Hoxsie et al. 2006), adapted and clarified in subsequent studies and which we quote below in its updated form as follows:

> A dispensing error is defined as any unintended deviation from an interpretable written prescription or medication order. Both content and labelling errors are included. Any unintended deviation from professional or regulatory references, or guidelines affecting dispensing procedures, is also considered a dispensing error (Franklin and O'Grady 2007, p. 277).

It is worth introducing a few clarifications here. The literature categorises dispensing errors into two main groups: *content errors* and *labelling errors* (Hoxsie et al. 2006).

Content errors include the dispensing of an incorrect medicine, an incorrect form (e.g., an extended-release product instead of a standard-release tablet), an incorrect pharmaceutical form (e.g., drops instead of tablets), an incorrect quantity (e.g., 12-tablet package instead of 24 tablets), an incorrect dosage (e.g., 10 mg instead of 30 mg), dispensing to the wrong patient, etc.

On the other hand, *labelling errors* are those occurring in non-standard, customised forms of dispensing based on a doctor's prescription. This way of dispensing is

prevalent in the United States, the United Kingdom and some European countries adopting galenic preparations. in this case, the pharmacy directly carries out the counting of the doses according to the doctor's prescription, its packaging, the printing of the label containing the identification data (e.g., active ingredient, dosage, quantity to be dispensed, etc.), the dosage and any necessary instructions for use. This can result in incorrect, incomplete, or illegible information, even if only due to the graphic or printing quality of the label (Ashcroft et al. 2005). According to Hoxsie et al. (2006), labelling errors account for the highest percentage of all dispensing errors.

A further clarification concerns the distinction in the literature between "dispensing error"—mentioned above and leading the patient to purchase a medicine that does not comply with the prescription—and "near-miss error".

The latter means any incident detected before the patient receives the medicine. For some authors, this includes all errors detected before the patient leaves the pharmacy (Ashcroft et al. 2005; James et al. 2009).

In the previous section, we gave a qualitative picture of the prescriptive errors detected in the dispensing phase, identifying their types, recurrences, and causes (James et al. 2009; Cheung et al. 2009) without dwelling on the quantitative data.

We follow the same modality in returning the analysis of the different types of errors in the dispensing activities. Here, we face different definitions and extremely diverse practices: from the dispensing of the medicine in the packaging produced by the industry—due to national and/or EU regulations, it cannot be opened at the pharmacy—to forms of dispensing which involve the pharmacist's packaging according to prescription. This process differs in manual, semi-automated or automated packaging (James et al. 2009). The regulations and procedures of the different countries are too different for any data comparison. We will focus on the different types of errors recurrently encountered to highlight the elements that, from a design perspective, could positively influence the process if redesigned.

8.2.3 Dispensing Errors: Methods and Data Retrieved from the Literature

The existing literature reveals the broad interest in dispensing and the related critical issues, with implications to be permanently focused on by various areas of study. Despite the consistency of the available studies and the wide variety of viewpoints, it is still complicated to fully understand the phenomenology of dispensing errors, as so many possible causes contribute to it. Suppose the sources investigated are almost redundant in confirming the types of error and the most recurrent underlying causes. In that case, interweaving the constituent factors and contingencies that converge in favouring a context permeable to error is more problematic. This co-causality is probably why defining the error environment is challenging to analyse, for determining actions to intervene and prevent. These can only arise from a systemic

perspective to promote multiple punctual interventions connected in an organic framework.

In the literature, the activities taking place within a pharmacy lie between two polarities: on the one hand, we find "quasi-phenomenological" definitions of the microdynamics in the procedural actions-operations (Ashcroft et al. 2005) and even the mental of the operators, filmed with audio and video while "thinking aloud" (Nusair and Guirguis 2017). On the other hand, we find a division of the context into individual elements separately analysed. In both cases, it is a problem that cannot be evaded when reflecting on the quality of the data collected and the possibility of using it by extending its scope to a broader scale. In the first case, the overemphasis on the peculiarities of the contexts and contingencies affecting pharmacy activity could lead to observations of a local nature.

In the second case, the research focusing on one or a few factors intended as variables capable of influencing error is judged by the authors as insufficient. Indeed, these studies emphasise the need to continue the research to assess the influence of the same factor at the change of context or, the need to supplement the assessment of a given element with subsequent analysis to verify how tight the correlation between the factor considered and the error found is (Weir et al. 2020). Finally, a broad literature concludes with the observation that the research carried out, even in the form of pilot projects, has rarely moved on to the implementation phase, even in the face of promising results, precisely because of the need to correlate individual actions within a broader framework of interventions (Weir et al. 2020). For these reasons, we have chosen to report below the most frequently found evidence in the literature, listed as restitution of a shared basis of recurring elements. These lists presented below, integrate different research sources (James et al. 2009; Ashcroft et al. 2005; Hoxsie et al. 2006; Cheung et al. 2009).

Types of recurrent errors in dispensing process:

- Error in reading the prescription;
- Error selecting medicine from drawer or shelf;
- Error in selecting dosage;
- Error in choosing the packaging with the prescribed number of doses;
- Error in choosing the pharmaceutical form;
- Error in choosing the release mode (e.g., normal/extended);
- Delivery of the medicine to the wrong patient;
- Delivery of an expired medicine;
- Delivery of a deteriorated medicine due to not properly storage;
- Missed assessment of the patient's general health condition (e.g. diabetes, pregnancy status, body pressure, etc.);
- Missed assessment of medicine allergies or intolerances;
- Missed detection of possible interactions with other medicines in the patient's therapy;
- Lack of, inadequate or incorrect instructions to the patient on the use of the medicine;

- Lack of, inadequate, or incorrect instructions to the patient on the storage of the medicine;
- Lack of, inadequate, or incorrect instructions to the patient on the proper disposal of the medicine;
- Filling the packaging with the wrong medicine (for customised dispensing forms);
- Incorrect tablet counting (for customised dispensing forms);
- Inadequate packaging of the medicine (for customised dispensing forms);
- Incorrect labelling/confusing label/label mix-up (for customised dispensing forms);
- Error in choosing the name and/or dosage from the selection lists in the software used to generate the labels.

The factors investigated as error-promoting causes also stem from integrating several sources and have been sorted into categories. Some of them can be placed in more than one category because they have been collected from different points of view. For example, "high workload" may be subjectively perceived and investigated as such (i.e., as a cause of inattention due to fatigue and stress). However, it may also result from poor work organisation (e.g., lack of staff, poor management of work shifts, assignment of tasks not pertinent to the role). A lack of knowledge may be a subjectively perceived weakness but may also result from a work environment that does not train staff. Factors most frequently cited in literature as contributing to dispensation errors:

Human/cultural factors (James et al. 2009):

- Lack of knowledge;
- Incapacity to understand/manage complex prescriptions;
- Poor dexterity;
- Poor predisposition to human interactions;
- Language proficiency;
- Workload;
- Number of prescriptions dispensed per hour;
- Stress;
- Fatigue;
- Hunger;
- Sickness;
- Job dissatisfaction;
- Lack of concentration;
- Patient's state of anxiety;
- Frequency of interruptions;
- Non-compliance with standard operating procedures.

Work organisation (James et al. 2009):

- Multitasking/monotasking;
- Role-based job description;
- Competence-based job description;
- Task-based job description;

- Work shifts;
- Absence of breaks;
- Staff inexperience;
- Quantity and quality of staff;
- Workload management;
- Lack of procedures;
- Failure to check;
- Lack of training;
- Lack of knowledge;
- Poor communication.

Environmental factors (James et al. 2009):

- Insufficient lighting;
- Sound pollution;
- Interruptions/distractions;
- Organisation of work areas;
- Organisation of storage areas;
- Criteria for arranging medicines in drawers and/or shelves;
- Logistics of incoming and outgoing medicine flows;
- Logistics of incoming/outgoing patient-customer flows;
- Presence of privacy areas.

Circumstances (Ashcroft et al. 2005):

- Busier than normal;
- Time of day;
- Not usual pharmacist;
- Not usual dispenser;
- Telephone interruption;
- Staff query;
- Customer/patient query;
- Busy over-the-counter trade.

Artifacts and process infrastructure (Ashcroft et al. 2005):

- Similar drug names;
- Similar packaging;
- Poor doctor's handwriting;
- Ambiguous prescriber's instructions;
- Computer software;
- Complex prescription;
- New prescription;
- Selection of the previous medicine or dosage from the patient's record on the pharmacy computer and not from the prescription.

Checking the appropriateness of prescriptions emerges as a recurring practice, starting with the patient's drug purchase profile, which can be found in the pharmacy's

computer history. This behaviour has been attentive because it can be misleading in all cases where the doctor has modified medicine characteristics or dosages with new prescribing indications (Chen et al. 2005).

As mentioned, the pharmaceutical dispensing process is complex and takes place in a working environment with multiple sources of risk, multiple types of errors and various phases in which errors can occur (Abood 1996). This exposure to erroneous actions subjects this environment to the interest of those who observe it as a socio-technical system (Szeinbach et al. 2007) with a high intensity of interaction between people, between people and objects, instrumental and technological aids, and between people and organisational artefacts necessary for the execution of complex tasks (Phipps et al. 2009). This is why various disciplines are studying it. For example, improving safety conditions is the focus of an area of study that introduces the 'human factor' as an object of interest in healthcare (Stojkovic et al. 2017; Weir et al. 2020). In this area, the interaction between people and the work environment is explored from the point of view of the physical activity involved in work operations; from the cognitive point of view, namely the mental processes involved; from the organisational point of view through the study of methods, tasks, structures, and activities (Harvey et al. 2015); and from the point of view of the sensory and perceptual factors that impact on the environmental quality of work activities. Important in this regard are Buchanan's work on lighting (Buchanan et al. 1991) and Flynn's work on the stresses that workers experience from environmental noise and visual chaos (Flynn et al. 1996), forerunners of this research field (Weir et al. 2020).

Several studies focused on subjective, psychological, motivational, and cultural factors, trying to establish a direct correlation between interpersonal skills, technical skills, specific skills and errors (Grasha and Schell 2001). Others have analysed the relationship between work overload, fatigue, and resistance to work-related stress situations (Flynn et al. 2002). Still, others have focused on the cognitive elements that induce error and the role that routine and work habits can exert in this order of oversights.

Others have focused on workflow management (Angelo and Ferreri 2005), staff organisation, defining and adhering to roles and job descriptions (e.g., adherence to a clear role distinction between pharmacist and pharmacy technician) (Ness et al. 1994; Flynn et al. 2002) or the pharmacist's failure to counsel the patient; failure to follow protocols or a tendency to deviate from codified practices (Jones et al. 2018).

Others have focused on the 'situations' that most expose to error or make dispensing problematic: first prescriptions or complex prescriptions; medicines that require technical advice (e.g., parenteral care, use of devices, dosages that need to be personalised); patients with multimorbidity; time pressure in dispensing; frequency of interruptions in dispensing operations; high number of daily prescriptions filled; multitasking work organisation (Flynn et al. 1999).

Studies and research on the incorporation and integration of new services (Szeinbach et al. 2007) and on the role of technology in streamlining procedures and reducing error (Bates et al. 2001) are equally substantial. Their focus has been on the use of electronic prescriptions and electronic health records, sensing technologies for authentication (e.g., such as barcode reading systems or radio

frequency identification tags) (Franklin and O'Grady 2007), barcode scanners to check and match whether the medicine selected from the shelf with the dispensing screen, and automated dispensing systems (Campmans et al. 2018). In detecting the positivity of the use of technology as an element of efficiency in the dispensing system as a whole, many of these studies have problematised the approach to technology as a miracle remedy and, alongside the aspects of positivity, have highlighted its potential adverse effects (Weir et al. 2020; Karsh et al. 2010) if the use of technological tools and infrastructure is not contextualised within the system of established practices and the more complex socio-cultural context.

8.2.4 Spatial Organisation and Environmental Factors

A further group of studies focused on the organisation of the pharmacy, analysed both as a workplace and as the internal environmental factors: all of these can favour a decrease in concentration or an increase in distraction and stress, producing a higher level of error (Weir et al. 2020).

For example, lack of space has been considered a cause of poor interaction between operators and users in dispensing activities, reduced privacy for the patient, and difficulties in recognising distinct operational areas of the work plan for each operator (Harvey et al. 2015).

These are necessary to avoid different operators having small or even partially overlapping or shared workstations and to ensure that the user can attend to dispensing prescribed medication. The literature presents errors in the delivery of therapy to the wrong patient (or the insertion of a medicine intended for one patient in another patient's bag), often made depending on workstations that are too close together or even shared. The identical sequences of technical actions (e.g., detaching the sticker from the drug, attaching it to the prescription, and numbering the prescriptions with progressive codes) would require a space that allows—and indeed prepares for—orderly operation (Lester and Chui 2016). These studies also highlight the usefulness of the patient's presence at dispensing activities (from reading the prescription, taking the drug in the required doses, and bagging it) for the "passive control" they can exert over the dispenser's activities.

One study verified the positive impact on error achieved using dedicated bins/trays for dispensing each patient (Hoxsie et al. 2006). In the absence of an autonomous workspace, sufficient in size to adequately organise the dispensing activity, the use of bins can have a positive effect. Indeed, the bins can be used to collect all prescriptions for an individual patient and all medicines to be dispensed, reducing the error rate detected by pharmacy staff.

Also, in studies on the organisation of space, we find that even the sub-optimal layout of furniture can increase errors and inattentions by generating interference between the daily flow of goods and patients upon entry, waiting and exit. Besides impacting the correct activity of operators, cluttered flows produce visual and acoustic chaos, distractions, and interruptions in staff activities (Lea et al. 2015).

Flynn et al. (1999) identified the interruption of activity (e.g., requests from colleagues, patients, handling of phone calls) as one of the elements capable of significantly influencing the error rate in dispensing activities (on these aspects see also Cheung et al. 2009).

Observational studies on the management of activities within pharmacies have also identified the organisation of work in multitasking mode (Dellve et al. 2018) as a possible source of increased error, suggesting that certain tasks (e.g., answering telephone calls, managing the sale of non-pharmaceutical products or service activities unrelated to dispensing activities) should be entrusted to dedicated figures (Hoxsie et al. 2006). Some authors assume that there is an essential difference between hospital pharmacies and community pharmacies; the staff of the latter are more prone to distractions and interruptions than in the hospital environment by selling a wide variety of non-dispensable items (e.g., devices, healthcare products, cosmetics, service provision) (Hoxsie et al. 2006). Hence, this applies especially to the role that pharmacy assumes in redesigning territorial systems of care. In fact, the new services offered by pharmacy staff include many activities previously the prerogative of other facilities/figures: administering vaccines, taking swabs, supporting health education, booking visits and examinations, providing laboratory tests, and monitoring basic body parameters. Moreover, while several studies have found the pharmacist's work to be characterised by high turnover rates and interruptions and distractions (considered the cultural norm), others have highlighted how commercial pressures create a conflict between the need for pharmacies to be profitable and the need for adequate resources (e.g., from staff to space) to maintain a safe working environment (Garattini and Nobili 2021).

A correct distribution of the different activities within pharmacies can be favoured or hindered by the workspace layout and the design of reserved areas to ensure a protected dialogue between pharmacists and patients.

The layout and organisation of the space are also fundamental in the arrangement of the medicine to be dispensed—both in the display on the shelf and the drawer because the easy accessibility of the medicine and its immediate recognisability depend on this. For the same reasons, importance is recognised in the organisation of stocks (Ruutiainen et al. 2021), which must also ensure the correct rotation of drugs according to expiry date and proper storage. Specific attention is paid to the criteria for ordering/cataloguing pharmaceutical items. The most common arrangement criteria are: the stock arrangement that separates branded and generic drugs, the arrangement that groups stocks according to pharmaceutical form (e.g. tablets, ointments, eye drops), the arrangement in alphabetical order regardless of pharmaceutical form.

8.2.5 The Role of Medicine Packaging in Dispensing

In the context of prescribing and dispensing activities, we have pointed out the incidence played by subjective factors or external environmental contingencies (e.g., noise, frenzy, inadequate workspace, lighting) that can induce or encourage error,

especially in a context in which several actors operate under conditions of insufficient communication. Although the result of distraction or superficiality in subjective action, some errors are strongly connected to the artefacts in use. We mainly refer to the 'communicative' ones that serve as tools for the passage of information between actors in a specific operational context—in the case under study, the prescription—and the medicines themselves.

As we shall discuss below, the formal and graphical-informative aspects of pharmaceutical packaging may be at the root of certain specific types of errors in both the prescription and dispensing process. Our attention in this section will focus on the latter. Like other products, the packaging of pharmaceuticals must ensure speed of packaging and low downtime during production, product protection, ease of identification during sale or dispensing, safe storage, ease of use and, at the same time, safety for the user. The quality of packaging must also ensure that the integrity of pharmaceutical products is maintained during storage, shipment, and delivery. At each stage of the product's life cycle—production, transport, sale, use, disposal—packaging must meet specific needs and have precise requirements.

For this chapter, we will analyse secondary packaging for the communicative and formal elements that can contribute to reducing or extending the possibility of error during dispensing in the pharmacy environment.

We will begin with an investigated aspect in the literature and about broad awareness in the medical-pharmaceutical environment. In this section, we will refer to the similar elements between different packaging, first and foremost, and specifically, to the similarity concerning the names of the medicines.

8.2.5.1 Name Similarities: Look-Alike/Sound-Alike Medicines

In the context of prescribing and dispensing activities, we have pointed out the incidence played by subjective factors or external environmental contingencies (e.g., noise, frenzy, inadequate workspace, lighting) that can induce or encourage error, especially in a context in which several actors operate under conditions of insufficient communication. Although the result of distraction or superficiality in subjective action, some errors are strongly connected to the artefacts in use. We mainly refer to the 'communicative' ones that serve as tools for the passage of information between actors in a specific operational context—in the case under study, the prescription—and the medicines themselves.

In the medical realm, the acronym LASA (Look-Alike/Sound-Alike) refers to medicines whose names can be mistaken for others due to their visual or auditory similarity (Bryan et al. 2020). Together with the class of medicines considered to be 'high-risk' or 'high-attention level' (in Italy, known as High Attention Level Medicines, *Farmaci ad alto livello di attenzione Farmaci—FALA*), because their misuse is associated with a high possibility of creating severe health damage for the patient (e.g., Insulins, Narcotics/Opioids, Sedatives, Anticoagulants), LASA medicines are under surveillance by the International Bodies dealing with pharmacovigilance (i.e., WHO, EMA, AIFA, FDA) and the Ministry of Health of the different

states (Berman 2004). Due to their similarity, the latter have compiled lists of pairs or triplets of medicines subject to recurrent reports of prescription or dispensing errors.

In Italy, an initial list of similarities was drawn up in 2008 by a working group mandated by the Ministry of Health based on more than a thousand reports collected spontaneously, mainly from hospitals and pharmacies. The working group created a database for statistically analysing data and assessing their recurrence. From this survey, the working group defined a list of LASA drugs (Ministero della Salute 2010a, b), the Ministerial Recommendation No. 12 (Ministero della Salute 2010a, b), and the LASA Medicines Table (Ministero della Salute 2015). In outpatient and inpatient prescribing/dispensing, LASA errors have long been the subject of research extensively documented in the literature (Ciociano and Bagnasco 2014).

Internationally, statistics of the incidence of this type of error and the severity that this exchange can produce are not supported by homogeneous data (Ostini et al. 2012). Still, the evidence that the LASA problem has in the literature is a sign of an issue that cannot be underestimated. Berman (2004) argued that LASA errors are responsible for thousands of deaths and, in the United States alone, result in millions of dollars in costs each year: more than 25% of all drug dispensing errors are attributable to LASA drug mix-ups and, in countries where dispensing involves packaging and labelling the drug at the pharmacy, this percentage rises to 33%. More generally, the rate of LASA errors found in the literature varies between 20% and 25% of dispensing errors in different countries. It poses a significant threat to the safety of patients who risk purchasing inappropriate or harmful medicines. For example, the United States Pharmacopeia recorded 26,604 LASA errors between 2003 and 2006, collected through spontaneous notifications (Lizano-Díez et al. 2020). Confusion between similarly named medicines affects all categories, from those for paediatric use (Basco Jr et al. 2010), to those for oncological use (Emmerton et al. 2020). With LASA drugs, the error can occur due to the similarity of the trade name of a drug pair or the similarity of the name of an active ingredient pair (which, in the case of equivalent drugs, coincides with the drug name), but can also occur between equivalent/speciality drug pairs (van de Vreede et al. 2008).

The error generated by a LASA medicine can occur either during prescription, transcription, or dispensing. In the case of prescribing, the role of the 'drop-down choice' typical of e-prescribing programmes is particularly highlighted. In this selection mode, medicines are listed in alphabetical order and, especially LASA drugs, are at risk of incorrect choice. In the transcription phase, this is mainly a hasty reading error of the original prescription. In the dispensing phase, the error can be generated both in reading the prescription and in selecting and taking the medicine from the drawer or shelf if two LASA medicines are stored next to each other. The error incidence is high when the similarity concerns the prefix of a medicine name because the most common order of arrangement of medicines in the pharmacy drawer is alphabetical (Bryan et al. 2020). LASA errors occur due to lexical elements shared by two or more names. Visually, the error is induced when the names of two medicines have identical parts with identical prefixes, suffixes, or desinences, or when the names are characterised by the presence of similar vowels and consonants even if arranged in a different order (Table 8.1).

Table 8.1 LASA medicines list updated to 2015—extract from Ministero della Salute

		Name similarity		Packaging similarity			
				Different active ingredient		Same active ingredient	
Medicine 1	Medicine 2	Phonetic	Graphic	Different component	Same component	Same component different dosage	Different component same dosage
Adalat 20 mg CPR	Adalat Crono 20 mg CPR		X			X	
Adrenalina 1 mg/1 ml FL	Atropina Solfato 1 mg 1 ml FL		X		X		
Adrenalina 1 mg/1 ml FL	Sodio Citrato 3.8% 1 ml FL				X		
Advagraf 1 mg CPS	Advagraf 0.5 ml CPS		X			X	
Aimafix 1000 UI 1 FL	AT III 1000 UI FL				X		
Aimafix 1000 UI 1 FL	Emoclot 1000 UI FL				X		
Alapril 5 mg CPR	Chiaro 250 mg CPR				X		
Alginor GTT OS Adulti	Alginor GTT OS BB		X		X		
Alfuzosina 10 mg CPR	Oxicodone 40 mg CPR				X		
Alkeran 2 mg CPR	Leukeran 2 mg CPR	X	X		X		
Amplital 1 g FL	Amplital 500 MCG Siringa preriempita		X			X	
Aranesp 20 mcg Siringa preriempita	Aranesp 40 mcg Siringa preriempita		X			X	
AT III 1000 UI FLAC	Uman Complex 500 UI FLAC				X		

(continued)

Table 8.1 (continued)

Medicine 1	Medicine 2	Name similarity		Packaging similarity			
				Different active ingredient		Same active ingredient	
		Phonetic	Graphic	Different component	Same component	Same component different dosage	Different component same dosage
Atenativ 500 UI FL	Atenativ 1000 UI FL		X		X		
Atked 1000 UI/20 ml FL Kedrion	Atked 500 UI/20 ml FL kedrion		X			X	
Atropina Lux 5 mg/ml 10 ml Collirio	Atropina Lux 10 mg/ml 10 ml Collirio		X			X	
Atropina Lux 5 mg/ml 10 ml Collirio	Ciclolux 10 mg/ml Collirio				X		
Atropina Solfato 0.5 mg 1 ml FL (monico)	Atropina Solfato 1 mg 1 ml FL (monico)		X			X	
Atropina Solfato 0.5 mg FL (monico)	Naloxone Cloridato 04 mg FL (produttori vari)			X			

The typeface (i.e., font, character body, colour) also contributes to accentuating the problem, especially in the presence of names with the same length that create a perceptual impact of similarity that overrides the effort of careful reading.

Similarity can also be detected phonetically, in spoken forms (e.g., names with similar lengths and sounds).

Starting from the lists drawn up by the relevant bodies, Berman (2004) proposed some useful examples to define real problematic categories that can occur in LASA designations:

- the names of two medicines differ by a few letters; in this category one can also find medicines used to achieve opposite effects;
- the name of two medicines has the same prefix or suffix;
- the name of two medicines has a common root;
- the sound of the name may be confused with that of another medicine.

LASA errors represent a *lapsus* (Trbovich and Hyland 2017), particularly related to processes of perceptual completion in which the reader's or listener's expectation and the brevity of the perceptual experience have a significant influence.

In addition, especially in the case of Equivalent Medicines where the name coincides with the active ingredient, the medicine names are "artificial" (Lizano-Díez et al. 2020); these names gain meaning only for the community of experts, whereas they are meaningless for end users (in particular, for patients). The difficulty in linking the medicine's name to a pathology precludes the patient from exercising conscious control over the medicines they purchase and, as we shall see later, does not help them better manage home medicine intake.

8.2.5.2 Packaging Similarity and Information Confusability

The interest in the phenomenology of error linked to LASA medicines has contributed to a specific focus on confusion arising from the similarity between names. However, this interest has also extended the focus to the problems of distinguishability of all those "elements" that should unambiguously identify the individual medicine: in addition to the name, the active ingredient(s), the dosage, the unit of measurement, the packaging graphics, and the overall shape of the packaging.

Many medication interchange errors arise from the plurality of information elements which, instead of being read in their individuality (e.g., name of the medicine, active ingredient, pharmaceutical form, dosage, number of doses per pack), are weakened by the "appearance" or graphic/typographical impression of the packaging. The packaging and its graphic elements (e.g., the shape and size of the packaging and the graphic/visual elements that make up the graphic layout) can contribute to accentuating the similarities between packages. It happens in secondary packaging of different medicines produced by the same pharmaceutical company: the visual elements that characterise the brand identity (i.e., font, colour, arrangement of the graphic elements on the page) increases the similarity between packages.

Examples of the difficulty in unambiguously distinguishing the information elements of the packaging due to inappropriate graphic treatment include dosage forms of the same medicine, confusing because they are similar and not sufficiently distinguishable graphically (e.g., 3.75 and 0.375 mg). The graphical appearance may contribute to accentuating or attenuating the possibility of error. However, dosage errors do not depend solely on their graphic treatment. In many cases, they result from interpretation issues related to how the dosage is expressed (Fig. 8.1). For example:

- two dosage forms of the same medicine whose units are expressed using different multiples (e.g., 500 mg and 1 g), thus hampering a rapid comparison of the amount of active ingredient contained;
- different pharmaceutical forms of the same active ingredient have different dosages and different units of measurement in the transition from solid to liquid formulation (e.g., mg, ml). This situation, which, if not properly handled at the prescription or dispensing stage, or using conversion tables included in the package leaflet, is likely to make it difficult for the patient to change the dosage (Lesar 1998; Madlon-Kay and Mosh 2023).

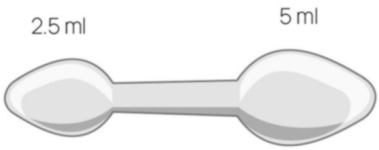

Fig. 8.1 Spoon dispenser of medicines containing acyclovir

Berman (2004) reports several errors concerning medicines administered intravenously in which the indication of the concentration on the label (40 mg/ml) quickly leads to the use of the entire packet (20 ml equal to 800 mg in total) instead of the correct dose of 40 mg. As well as highlighting the errors that can arise from the concentration of the same medicine expressed with different dilution ratios (e.g., 1:1000 or 1:10,000) or as a percentage (e.g., 1% or 2%). Each of these examples brings reconversion problems that doctors find difficult to deal with.

Medicines are present in the same pharmaceutical form with concentrations expressed in different units. For example, antiviral medicines containing acyclovir are available either as syrup, 8% suspension of 80 mg/ml, or as an oral suspension of 400 mg/5 ml. The presence of the measuring spoon can be helpful, but, since the patient's weight affects the medicine prescription, the conversion to the customised dose is not always easy. To solve this conversion issue and obtain the correct dosages, tips, procedures, and indications can be found on the web: a sign that the problem arises despite the patient receiving instructions from the doctor. For this reason, the Italian *Ministero della Salute* has returned to the issue with several Recommendations: Recommendation No. 7, Recommendation for the prevention of death, coma or serious harm resulting from errors in drug therapy (Ministero della Salute 2008); Recommendation No. 18, Recommendation for the prevention of errors in treatment resulting from the use of abbreviations, acronyms, acronyms, and symbols (Ministero della Salute 2018).

Moreover, in many cases, these are medicines used in emergencies, such as in Emergency and Resuscitation Units (Pérez-Moreno et al. 2017). The researchers have focused heavily on emergency units, believing that these are where the likelihood of error resulting from confusion between the names and packaging of similar medicines is most probable. This occurrence depends on the frequency of verbal orders, crowded storage spaces, and the need to quickly administer high-risk index products and medicine classes in which names are more frequently confused (Fig. 8.2). Add to these circumstances the presence of patients whose medical history is not known in depth nor, necessarily, is there any knowledge of the therapy in use (Hellström et al. 2012).

In addition to the critical points mentioned above, further elements that can make reading the medicine's 'master data' complex are graphic and concern:

- the alteration of the font shape or the use of multiple colours to visually compose the name (Fig. 8.3);
- the name/logo of the company brand which, placed close to the name of the medicine, may lead one to believe that it is part of the name itself;

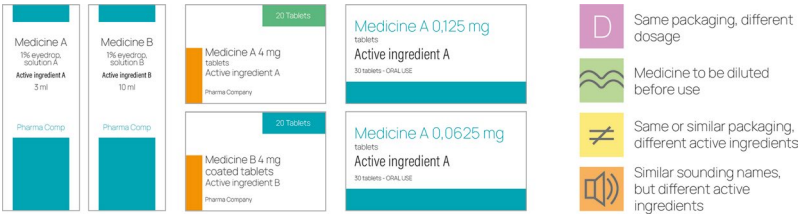

Fig. 8.2 On the left, examples of ambiguity problems in the reading of graphic elements; on the right, examples of symbols used by nursing staff in hospitals indicate LASA medicines

Fig. 8.3 Exemplification of medicine names with changed typography or the use of multi-coloured fonts

- the information given in the Braille alphabet, which may create optical interference and not allow certain information to be read correctly if overwritten with other visual elements (Fig. 8.4);
- the dosage of the active ingredient is placed next to the name of the medicine or sometimes in an isolated space on the main face of the packaging (Fig. 8.5). It is well known that this complies with current legislation, particularly with Directive 2001/83/EC, which states in Art. 54(a): *"The name of the medicinal product followed by its strength and pharmaceutical form"* (The European Parliament and of the Council 2001). However, we believe that this information element, since it refers to the dosage of the active ingredient, should more appropriately be placed close to it to form a "meaning unit" and make the information on the medicine to be dispensed comprehensible. We will discuss this aspect in Chap. 22.

We have so far addressed some of the problems with the information elements on secondary packaging, which can contribute to errors in dispensing (Fig. 8.6). A final consideration regarding secondary packaging concerns its shape: in addition to optimising the use of shelf or drawer space, this must ensure easy readability of the information. On the first side, we can cite the problems generated by those packages that are too far removed from standard formats (e.g., the cubic pack of D.L-lysine acetylsalicylate sachets, which does not respond well to optimal use of

Fig. 8.4 Example of a problem of visual interference generated by overlapping the Braille characters the name of the active ingredient or by using lettering without the necessary visual contrast with the background

Fig. 8.5 Example of a medicine containing two active ingredients. The information indicating the dosage and the two active ingredients are not connected

Fig. 8.6 Example of medicine names that cannot be distinguished from the manufacturer's name. On the right, the 'registry' elements identifying different medicines generate significant ambiguity

space in pharmacy drawers; or medicines whose shape does not allow for shelf-stackability). On the second side, we can mention all cylindrical-shaped packs that do not guarantee a rational use of space and do not allow optimal reading of the information on the curved surface. Or again, packs which, due to the size of the base and the base-to-height ratio, risk not guaranteeing the balance of the packaging in the shelf display. The supply chain phase of pharmacies by dispensers should also be carefully considered. For instance, there is a lack of design of the tills used to restock pharmacies to separate heavy medicines (e.g., syrups, vials) from fragile ones (e.g., blister packs). It is common for blister packs to arrive at the pharmacy damaged or crushed due to the random distribution of

medicines in the supply case. In addition, medicines that need to be refrigerated represent a significant issue. What is lacking to date is a 'cold chain' system designed to reach the patient. The mode used is that of ice packs that are 'tied' to the medicines by rubber bands or refrigerated bags not explicitly designed for this function. In addition to being logistically problematic systems, they are also environmentally inefficient because many of these ice packs accumulate in the patient's hands and are then thrown away.

8.3 The Role of the Prescription in Dispensing

Prescriptions are the main document with which the doctor prescribes and communicates to the pharmacist the 'identifying' information of the medicine(s) to be dispensed to a specific patient (Al-Khani et al. 2014).

The doctor can write directions manually or by typing on a computer. The prescriptions can have a paper format and be directly given to the patient or have an electronic format and be viewed instantly by the pharmacist in digital format.

In being a prescriptive document, the prescription:

- authorises the patient (not imposes) the use of pharmacological substances;
- defines the active ingredient, the dosage, the pharmaceutical form, the doses of medicine per pack and the number of packs that can be dispensed, as well as indicating the name of the patient, the prescribing doctor, the date of prescription, and the doctor's signature;
- starts a treatment process that must be followed over time to verify—also by specific diagnostic tests—its efficacy and any side effects.

Prescriptions do not contain:

- indications relating to the instructions for the use of the medicine;
- indications relating to the dosage;
- indications specifying the specific medicine prescription;
- indications relating to examinations required before starting or for chronic use of a medicine;
- indications concerning the interval that must be observed before dispensing a subsequent refill.

In the Italian context, prescriptions represent an exclusive dialogue 'tool' between doctors, pharmacists, and the National Health System concerning the administrative part of exemptions. Indeed, the pharmacist collects the prescription and is obliged to keep it for 6 months, except for prescriptions that must be sent to the National Health System for the envisaged refunds. Instructions on use and dosage, as well as why a specific medicine is prescribed, are provided by the doctor to the patient on a separate medium or are sometimes given verbally. This information is not accessible to the pharmacist unless provided directly by the patients. On the other hand, the patient is left with no trace of the information in the prescription unless accessed through the personal electronic health record.

Precisely because of these characteristics, the prescription assumes a limited role that ends with purchasing the medicine. Since it does not contain the information capable of connecting the 'authorisation to purchase' to the acts of treatment, it must be accompanied by other information devices. These are necessary to provide the patient with the information needed to take the medicine correctly and to understand the reasons for prescribing it (among these, we can mention the hospital discharge letter, the document brought to the attention of the treating physician by the specialist after the examination, the indications issued by the general practitioner in written or oral form with the dosage). These indications to the patient could also be helpful to the pharmacist in intercepting possible prescription errors or while dispensing them (Kennedey et al. 2011).

The logistics of the prescription itself increase the potential for error. Especially when it comes to repeated requests for chronically consumed medication, the doctor fills the prescription on the patient's instructions through the intermediary of the outpatient secretarial staff. This request for the medicine(s) is written on paper (sometimes without the patient's full name) and may also be dialled over the phone. After completion, collection by the doctor may be done by the office staff, but the patient frequently picks up the prescription from a special box in the waiting room of the doctor's clinic. These poorly regulated arrangements, while facilitating the user, can, on the other hand, lead to dispensing medicines not explicitly prescribed to a patient (Hoxsie et al. 2006). This occurs also because the pharmacist is not required to verify the relationship between the prescriber and the patient to whom the prescription is addressed.

The automatism with which the prescriptions for chronic intake are issued has the effect of introducing the taking of the medicine itself into a routine procedure, often without the necessary checks on efficacy or side events, which, especially in the initial stages, should be monitored by the doctor. The same automatism also intervenes to the detriment of any diagnostic examinations that should be carried out periodically to continue taking the medicine, whereas, once the therapy has begun, these examinations are not always carried out even though it is the package leaflet itself that indicates the advisability of doing so.

A final remark can be made on placing the medicine sticker on the prescription. This operation, which pharmacists are obliged to do and which serves above all for exemption of the medicine (so that the pharmacy can receive the reimbursement provided for), is still not helpful in matching the prescribed with the dispensed. This type of matching would require a switch to the electronic format of the prescription so that its code can be compared with the identification code of the medicine dispensed (on the potential of the electronic prescription, see Chap. 9 of this text).

In the switch to electronic prescriptions lies the hope of solving many problems connecting prescription and dispensing. E-prescribing has already revealed many potentials that could not be addressed with current paper prescriptions. To be expressed, these potentials require a systemic approach to the prescribing act capable of integrating a set of information that currently resides in different, unconnected documents (Ammenwerth et al. 2008). The actors who must intervene in the several steps of the process have a fragmented view of the patient and care-related

knowledge. Some studies demonstrate how the redesign of the prescription, especially in electronic format, can reduce errors in prescribing and dispensing but also influence the physician's choices regarding treatment options. Malhotra et al. (2016) show how the redesign of the prescription interface, in providing predefined opportunities in the selection of medicines, strongly influences physician behaviour (Odukoya et al. 2014). The hierarchical order given to the information, in fact, implicitly acts as a recommendation.

Studying the effect of warnings on medicine interactions, Luna et al. (2007) report a high tendency to underestimate these signals due to the large number of warnings concerning clinically irrelevant interactions.

These are only a few examples, but they are adequate to show how the transition to technological prescription forms must result from careful planning.

Studies that have specifically examined the use of electronic prescribing technology (Weir et al. 2020) have pointed to an increase in the cognitive load on staff when storing information, an increase in inappropriate interpretations of prescriber information by pharmacy staff (e.g. for text boxes that cannot contain the full range of medicine indications), improper use of the 'drop-down' system in the prescriber's choice of medicine and patient, automatic selection of the medicine and/or dose based on the patient's previous purchases (Odukoya et al. 2003, 2014; Franklin and O'Grady 2007; Odukoyn and Chui 2012).

In conclusion, we report some indications emerging from a study aimed at detecting prescription errors at the dispensing stage and how they effectively prevented or intercepted them. In hospital pharmacies where the pharmacist could access patient data (Al-Khani et al. 2014), the research found the opportunity to dispense the required medication more consciously and safely and prevent some prescription errors. The factors that contributed to the identification of prescription errors, before the dispensing of the medicine were:

- the verification of the prescription indication of the medicine;
- the examination of the patient's medical history;
- examination of the patient's pharmacological history;
- an interview with the prescribing doctor;
- counselling the patient during dispensing.

8.4 Towards a Proper Dispensing

Prescribing a medicine, with the assessment of its necessity, the selection of the correct active ingredient, the personalisation of therapy, and the definition of the expected therapeutic response represents the completion of the complex activity of clinical assessment. However, prescribing a medicine is not a matter of closing but of starting a process that must be followed over time, monitoring the patient's response, identifying, and reporting any adverse events, re-evaluating the choice of medicine, the regimen, and the frequency and duration of treatment. It is a process

in which collaboration and communication between healthcare professionals is essential, as well as the involvement of the patient, who must be educated about pharmacological care and trained in medicines.

Especially when the patient is faced with complex therapies—this is the case, for example, of the elderly patient or, in general, of the multi-disease patient—an activity of direction, review, and reorganisation of the patient's complete therapeutic regimen is also necessary.

The doctor, the pharmacist, and the pharma industry—through the package leaflet—play relevant but, at the same time, poorly connected and, therefore, deficient roles. For the patient, it is also unclear who to address for information about the treatment and its management, and the fragmentation of information, in addition to the ambiguous role played by the various actors involved in the process, means that the pharmacist's role is also not correctly understood. To some extent, the goal of improving communication and information sharing between general practitioners and pharmacists rests on the expectations of improvement entrusted to the use of technology (e.g. e-prescribing systems, electronic medical records, electronic patient drug history). However, the incentives for increasing services within the pharmacy activities should be carefully observed. This push towards a service pharmacy could take a commercial drift, effectively taking time away from patient counselling. Counselling constitutes a fundamental support for proper dispensing, as defined by Article 12 of the pharmacist's Code of Ethics.

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