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Antonella Valeria Penati *Editor*

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

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Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

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Chapter 7
Moving the Care Process in the in-Home Context: The Therapeutic Prescription

Carlo Emilio Standoli, Milena Giovanna Guarinoni, and Enrico Morello

Abstract After a medical consultation or hospitalisation, when the patient returns to everyday life, how is the correct adherence and therapeutic continuity guaranteed according to the indications given by the clinician, especially when it comes to multidimensional therapy (e.g. pharmacological, rehabilitation, etc.)? Do clinicians and hospitals use communication strategies and tools to give indications—through prescriptions—of sometimes complex therapies to be followed effectively? Moreover, what tools does the patient have to tell the general practitioner about the therapies in use or support therapy management at home? In the specific case of medicines, what dialogue is established between doctor and patient to assess the appropriateness of their prescription, considering not only clinical needs but also the patient's lifestyle and preferences? The chapter addresses the process of transitioning care from the hospital to the home setting, presenting the different phases and issues that, on the medical side and the patient side, are experienced from the moment of prescription. The emerging reflections form the basis for formulating perspectives for future models of transition of care and discharge.

7.1 From Hospitalisation to Home: The Discharge Process

Looking at the discharge process without going into the peculiarities of the wards' specialities and the acuity and severity of the patient's condition, the discharge process begins when a patient is considered sufficiently cured to continue care elsewhere, whether in the home setting or another healthcare facility. In the Italian context, in the implementation of the organisational model of the territorial care network (Ministry of Health 2022), home care is to be strengthened, both through

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home-based services and telemedicine, with the support of centres such as the Case di Comunità (Community Centres), in which general practitioners and other specialists are located. With this in mind, hospitals are mainly delegated to intensive care (Ministero della Salute 2024). This structural and organisational change in the health system makes it possible to reduce hospitalisation times by promoting territorial management of the patient: continuity between the hospital, the territory and the home context thus assumes a crucial role. If one then examines the dimension of punctual knowledge of pharmacological therapy, it is necessary to be aware of all the information to manage the patient from the moment of admission, during the period of hospitalisation and at the time of discharge. This precise knowledge represents a guarantee for continuity and adherence to treatment and to avoid any accidental and unintentional discrepancy, which could represent a risk for the patient (Ministry of Health 2014). Precisely to address these risks, the World Health Organisation (WHO) recommends Pharmacological Recognition and Reconciliation interventions aimed at preventing medication errors in the transitions between hospitalisation and return to the home setting (Ministry of Health 2014; WHO 2017).

Pharmacological therapy recognition refers to the process by which information is collected in a systematic, accurate and complete manner on the medicines taken by the patient: this recognition concerns medicines classified by the Italian Medicines Agency (AIFA) subject to restrictive prescription, medicines without prescription (*Senza Obbligo di Prescrizione*—SOP), medicines over the counter (OTC), and even homoeopathic medicines, phytotherapeutic medicines, and possible behaviours such as drug taking, smoking and alcohol consumption. Concerning medicines, the information that is collected is (Ministero della Salute 2014)

- the commercial name and/or active ingredient;
- the pharmaceutical form;
- the dosage;
- the daily dosage;
- the start date and duration of therapy;
- the date and time of the last dose taken (with particular attention to long-acting formulations);
- the route of administration;
- any experimental treatments, including compassionate use and off-label drugs (in particular the therapeutic indication);
- the intake of homoeopathic, phytotherapeutic and supplementary medicines and any other product of non-conventional medicine;
- the presence of known pathologies, allergies or intolerances;
- previous therapies and any undesirable effects;
- intake of foods (high doses of grapefruit, coffee, tea, fruit and vegetables) that may interfere with the therapy;
- the patient's weight and height data;
- lifestyle (possible alcohol intake, smoking and drug use);
- use of medicated medical devices;
- any other data considered significant.

Usually, it is appropriate for the patient to communicate all these data as they are not only therapeutic, but also behavioural and routine in nature; alternatively, in extraordinary cases such as the patient's non-cooperation, demographic factors such as age, or other cases, a family member or caregiver may communicate this information. In the latter case, the doctor must keep track of the source, in case of subsequent changes and additions.

In the ward, before the adoption of a new pharmacological therapy or the integration or substitution of certain medicines (e.g., by active ingredient, dosage, pharmaceutical form, possible drug interactions, etc.), the physician double-checks the Reconciliation document and compares it with what should be the new treatment plan. This phase, called reconciliation, serves to identify any inconsistencies between the treatment plan or critical issues such as interactions, contraindications, possible confusions due to Look Alike Sound Alike Drugs (LASA), and all the information released by AIFA. Regional procedures concerning the *Prontuario Terapeutico* (therapeutic handbook) and territorial continuity management are considered in the Italian context. In the two stages of recognition and reconciliation, the hospital pharmacist always supports the doctor. The person in charge of monitoring and taking charge of the management of the patient's drug therapy on the ward is the ward nursing coordinator.

In these two phases, the physician must communicate effectively with the patient, family members, and caregivers. In the reconciliation phase, dialogue is essential to understand the pharmacological plan and any factors that may influence it; in the reconciliation phase, it is necessary to inform and make the patient, family member and caregiver understand the modification actions that will be implemented. In fact, the patient should be informed about aspects related to the therapy in the strict sense (e.g. possible risks and contraindications, dosages, pharmaceutical form, etc.) that could influence acceptance and adherence to the therapy in the ward context. This first level of communication about the therapy may also form a basis for the establishment of trust and an ongoing relationship between the patient and the ward healthcare staff, another element that may influence acceptance and adherence to the therapy in the hospital setting and subsequently in the home setting (WHO 2017).

As mentioned above, at the end of the hospitalisation period, when the ward staff considers that the patient can be effectively treated elsewhere or is sufficiently healed, the hospital discharge process begins. Usually, this process is divided into two phases: the first one, which is managed by the medical staff, consists of a concluding visit in which all therapeutic activities (e.g. drug therapy management, rehabilitation activities, nutrition management, forthcoming outpatient/ambulatory meetings, etc.) detailed follow-up instructions are also communicated. In addition, the physician should ensure that the patient, family member or caregiver has correctly understood all the information. The doctor is also in charge of updating the pharmacological therapy, with an additional recognition and reconciliation analysis, and completing the discharge letter, which the patient will hand over to the General Practitioner. The second phase, managed by the nursing staff, delivers all the material, from the medical record to the discharge letter. Then, the nursing staff reinforce the pharmacological management with medication boxes and an explanation of the

correct medication management (e.g. medication to be kept in the refrigerator). Any deadlines for medication of central venous accesses or wounds are recommended.

The discharge letter is one of the tools allowing continuity of care and assistance because it puts the ward from which the patient is discharged in contact with the general practitioner and the specialists who will take care of the patient. The discharge letter is structured on the basis of regional guidelines and must take into account this information:

- the patient's personal data;
- the reason for admission;
- date of discharge;
- objective examination;
- procedures performed (e.g. laboratory tests, instrumental tests, consultations, reports, etc.);
- diagnosis;
- diagnostic and/or therapeutic programme and follow-up;
- any prescribed therapies at home;
- any new appointments for outpatient examinations or subsequent hospitalisation or inpatient stay, or new examinations to be taken;
- personal data and signature of the doctor.

The discharge letter may include information sheets for nutrition and self-care management. Concerning pharmacological therapy, the specialist doctor reports in the discharge letter both the therapy prescriptions necessary to medicines' dispense, and the discharge therapy proposals, i.e. the indications for the decision of competence addressed to the general practitioner (Emilia-Romagna Region 2024).

When compiling the new therapeutic plan, the doctor must ensure that the selected drugs comply with the prescriptibility and appropriateness rules indicated in the AIFA Notes (AIFA 2023), which define the reimbursability of the drug at the expense of the National Health System (*Sistema Sanitario Nazionale,* SSN); the impossibility of charging the SSN is reported; the active ingredients are present in the *Prontuari Terapeutici Aziendali*, to guarantee greater affordability of the drug (Regione Veneto 2023).

In the therapeutic prescription document, depending on the patient's needs, the doctor may indicate the following types of medicine (Regione Veneto 2023)

- Medicines subject to specialist prescription, namely all those medicines listed by AIFA as subject to prescription and which require a dematerialised or red paper prescription, and class C medicines and not reimbursed by the SSN, which require a white prescription on the doctor's letterhead;
- non-prescription medicines, namely those recommended by the hospital specialist doctor, subject to a repeatable, non-repeatable, or non-prescription prescription. In this case, the hospital specialist doctor will indicate the active ingredient, and then the general practitioner will fill out the dematerialised prescription or red paper prescription. As in the previous case, the hospital specialist will fill out the white prescription on letterhead for class C medicines, and the patient can purchase the medicine at their own expense.

- Medicines used for acute treatment, namely those medicines for which the hospital specialist may directly fill a dematerialised prescription or red paper prescription and which can be dispensed directly from the hospital pharmacy. In this case, the hospital specialist will fill out a white prescription on letterhead for class C medicines, and the patient can purchase the medicine at their own expense.

In specific cases, the hospital dispenses certain medicines to safeguard the continuation of the patient's care outside the hospital setting, guarantee a quick start of the therapy, and support proper adherence (Regione Veneto 2023).

Due to many factors, such as organisational (e.g., the amount of time spent by medical staff on communication with the patient, or the amount of information to be managed and assimilated in a short time by the patient or caregiver), social and cultural (e.g., the degree of medical literacy of the patient, family member or caregiver, or knowledge of the language), emotional (e.g., the vulnerability of the patient, the degree of stress due to admission or discharge), make the moment of care transition and discharge highly critical for the proper passage of information between hospital, territory and patient, and potentially at risk of re-hospitalisation (Forster et al. 2003; Jencks et al. 2009). Especially in the transition from acute to chronic patient, and in the case of patients with multi-morbidity and polypharmacy, it is necessary to understand the leading causes for non-adherence to therapies to develop strategies and implement virtuous mechanisms to support home care and therapy.

7.2 The Discharge Process' Actors

In the discharge letter, the hospital specialist indicates the therapy to be followed at home, having multiple interlocutors. The transition of care from hospital to home is a complex phase involving the specialist, the hospital nurse, the general practitioner, the patient, and, if needed by the patient, the caregiver. The integration of these players, through a greater understanding of the social and health needs and the patient's wishes, through health literacy, leads to improved health outcomes in patients who have to undergo long-term home care.

An ever-present interlocutor is the general practitioner, the professional who takes over the patient's care once discharged. The general practitioner prescribes the person's medication once at home and, therefore, becomes the basic interlocutor. The general practitioner may agree with the hospital specialist and, therefore, continue with the prescription indicated in the discharge letter, or disagree and introduce changes to the hospital's recommendations. The motivations that may lead the general practitioner to make changes in the therapy may be manifold: knowledge of the patient's overall clinical situation (e.g. concomitance of other therapies, lack of efficacy of the molecule in the long term, etc.), but also of the social situation (e.g. impossibility of managing parenteral therapies, etc.).

Another interlocutor of the hospital prescribing specialist is the person responsible for the practical management of the therapy administration. This figure may be the caregiver (for patients such as children, elderly, disabled, etc.), or the patient themselves. The caregiver is a figure who may be a family member or takes care of the person at home for work. Whoever the caregiver is, in the transition between the hospital and the home, they must manage the therapy precisely prescribed by the hospital, respecting the correct medicine, route of administration, dosage, and time.

However, the hospital specialist prescriber's main interlocutor remains the patient, with the burden of experiences, knowledge and education. If, during hospitalisation, the patient can live an experience of "reliance", willingly accepting all that is proposed in terms of therapy, when returning home, the patient experiences a re-appropriation of their life and habits, which may lead them to experience therapy differently from the hospital situation. For this reason, the hospital prescriber should first share the therapeutic pathway with the patient, listening carefully to the needs and wishes of the patient, who is the subject of their own health.

7.2.1 The Acute Patient

Complex patients discharged from ultra-specialist wards (e.g. bone marrow transplantation) represent the borderline information management case between hospital and home. The discharge letter represents the instrument on which therapeutic prescriptions are implemented at the patient's home with the caregiver's contribution and the general practitioner's supervision. In this setting, the general practitioner often does not represent a resource because the specialist department still manages the post-discharge course. Furthermore, the polypharmacological management of therapies, including immunosuppressants, whose plasma monitoring is performed by the hospital, excludes the general practitioner from being an active part of the process. The discharge letter is presented as the first information tool and is explained using an interview as accurately as possible, specifying the indications that emerged from admission, the drugs recommended at home and the subsequent follow-up:

- indications on admission: the discharge letter presents a large body of information structuring the hospital course based on the clinical course and the main events recorded during admission. The final part of this section identifies the main unresolved or ongoing clinical elements that the general practitioner or post-hospitalisation specialists can take care of.
- Pharmacological therapy is usually prescribed in order of importance according to the specialist's treatment principles (e.g. immunosuppressive drugs first, then anti-infectives, then those for any comorbidities or ancillary to the treatments as mentioned above). All drugs are usually indicated with the active ingredient (sometimes with the trade name if the active ingredient is too long or complex), the recommended dosage, and the administration time. If necessary, a section

may be supplemented with nutritional supplements, vitamins, and foods for particular medical purposes.

The last section indicates the recommended behaviour at home under normal conditions and in the event of complications (e.g. fever, respiratory difficulties, diarrhoea, etc.) and the subsequent day hospital or outpatient appointments and the behaviour to be adopted (e.g. do not take immunosuppressive drugs before their plasma dosage is taken).

7.2.2 The Chronic Patient

In oncology, the development of molecular-targeted therapies has enabled the chronic treatment of patients previously only eligible for chemotherapy. The relative manageability of such treatments has made it possible to treat an increasingly elderly population with various comorbidities. In this setting, therefore, elderly patients are forced to handle increasingly complex therapies. A helpful tool for the home management of drugs can be colour coding. According to a specific criterion, therapy sheets with coloured charts are printed, and envelopes of the established colour are prepared to contain the prescribed drugs. In this case, management by the patient and caregiver can be facilitated by referring to certain times of the day and possible therapies as needed. To further reduce errors, a healthcare professional's constant monitoring of the treatment, prescription sheets, envelopes, and any deadlines would be recommended.

7.3 Home Care Between Therapeutic Adherence and Non-adherence

With the progressive increase in life expectancy (WHO 2021) and with the definition of new paradigms of care that tend to empower the patient, one's family, caregivers and community medicine, the correct adherence to therapy—not only pharmacological—becomes crucial for the well-being of the person.

In the case of pharmacological therapy, we can refer to adherence as the extent to which a patient takes medication as indicated and prescribed by their doctor (Osterberg and Blaschke 2005). Pharmacological therapeutic adherence has to consider the achievement of two main goals related to medicine consumption: the prescribed modalities, namely taking into account the type of medicine, the timing, the quantity, and the consumption patterns, and the time, namely taking into account the constancy and continuity in taking medicine (Brown et al. 2016).

It is easy to administer the right drug when there is only one or two to manage. However, if we think that, often, the patient takes a multiplicity of medicines, it becomes complex: at 8 a.m., which medicines do I have to take? Which ones are on

a full stomach, and which should be taken between meals? Speaking of administration routes, it is relatively simple if I have tablets to take orally (actually, problems may arise if the patient is unable to swallow a tablet and it is not known whether it can be crushed, dissolved in a liquid, etc.); it gets more complicated if the route is parenteral, rectal, etc. Speaking of dosage, if it is stated 'one tablet in the morning, two in the evening', there should be no problem understanding; it is different if the indication is 2 g × 2, or 150 ml every 12 h.

All this, together with the correct home storage of the medicines (bear in mind that some medicines must always be stored at controlled temperatures, in their original undamaged packaging; some, once reconstituted or diluted, must be consumed in a very short time, etc.), and the control of expiry dates, makes the management of the medicine at home much more complex than in the hospital environment where professionals are trained in these aspects.

In the home setting, it is very challenging to acquire qualitative and quantitative data on therapeutic adherence and, of all the tools to acquire data (e.g., questionnaires, interviews, self-reporting, instrumental analysis), none of them can be considered accurate and precise (Lavsa et al. 2011). Causes that may influence adherence include factors such as the complexity of the therapy or drug interaction, as with LASA (Giannetta et al. 2019), socio-demographic, socio-cultural and socio-economic factors (Napolitano et al. 2016; Sampaio et al. 2020), non-understanding of pharmacological therapy (Napolitano et al. 2016; Pasina et al. 2014) or prescription errors (Dionisi et al. 2022), patient's beliefs and concerns concerning treatment (Hughes 2004; Osterberg and Blaschke 2005), the relationship with one's doctor (Phatak and Thomas III 2006; Gallé et al. 2021), factors related to the physical characteristics of the drug or its management and accessibility (Jansà et al. 2010; Napolitano et al. 2016), or lack of motivation concerning the care pathway (Brown et al. 2016), especially among chronic patients, or the absence of a caregiver.

The data concerning polypharmacy are substantial: in Italy alone, among people over 65 years of age, at least a quarter of them consume at least 10 different medicines daily (AIFA 2024), increasing the risk of error due to forgetfulness, confusion between types of medicine, drug-drug or drug-food interactions, reduced motivation, etc. Voluntary withdrawal or its modification without medical consultation—due to a lack of motivation or a perceived change in health status, for the better or for the worse—are among the most recurrent causes of non-adherence (Pasina et al. 2014). Another phenomenon observed is what is referred to as 'white coat adherence': adherence and compliance vary in the period between two medical visits, as the patient changes his or her drug-taking behaviour just around the time of the visits (Osterberg and Blaschke 2005; Pasina et al. 2014). This behaviour also generates difficulties in defining the actual adherence to therapy with clinical analyses.

Therefore, many concauses influence therapeutic adherence. First and foremost, the human factor, including the patient, family members and caregivers, and general practitioners, hospital specialists and nurses, through to pharmacists. The complexity of communication is seen from the perspective of language and literacy, as well as the ability to empathise. The medicine in its material, formal dimension, how it is consumed and the gestures and rituals it creates. The complexity of the processes,

from prescription to dispensing to consumption. Reflection on therapeutic adherence requires a reflection that is not reductionist, linked only to therapy compliance, in other words as that passive behaviour in which the patient follows a list of instructions from the doctor (Mir 2023), but from a transdisciplinary and people-centred perspective, starting from the patient to the medical and healthcare personnel.

7.4 Perspectives to Support a Person-Centred Transition of Care

Prescriptive appropriateness, meaning prescribing the right medicine to the right patient at the right time, requires an accurate quality pathway to ensure patient safety. This pathway is left to the initiative of individual patients. However, it needs to be better structured already in the planning phase of the treatment pathway, integrating the patient's needs according to their requirements (e.g. education, social context, IT skills, etc.) with the needs of professionals. A collaborative process between the different actors involved could support defining the best prescriptive pathway for the individual patient.

In this sense, a first perspective of intervention concerns the patient's discharge process. The patient is truly ready for discharge concerning the time spent communicating and verifying all the necessary information (Facchinetti et al. 2021), to rehearse the care processes that will have to take place in the home context. This training must also involve family members and caregivers, who are very often the ones who take charge and are the custodians of the information of the entire care process (Bragstad et al. 2014; Hagedoorn et al. 2017). A hasty discharge preparation, without the active involvement of family members and caregivers, in the absence of empathy towards what the patient feels, with partial or wrong information, is the first step towards a subsequent re-hospitalisation of the patient.

A perspective of intervention may, therefore concern nursing education and practice, both within the hospital as well as in the territory and at home: the period of transition of care should consider practical and organisational aspects and an increase in the time spent with the patient, to transmit and verify knowledge and skills appropriate to the management of therapy. The nursing staff should be recognised and valued as the guarantor of the transition and continuity of care (Facchinetti et al. 2021). Successful transition of care and discharge also depends on designing interventions and activities that are adapted to the patient's characteristics, skills, and beliefs (McDonald et al. 2002), thus abandoning the reductionist dimension of care to consider the individual's complexity.

The transition of care and the move to the home setting must not represent the end of the relationship between the patient and the staff who cared for the patient. In this, the role of the General Practitioner and their involvement before discharge and during the transition of care becomes paramount (Facchinetti et al. 2021). In addition, the use of different platforms for communication, from telehealth to

e-health to more accessible objects and applications adapted to the home context, may represent further levers for increasing motivation and improving therapeutic adherence.

Providing clear and timely instructions and reducing the complexity of pharmacological therapies as much as possible can be further levers towards adherence to medication regimes (Pasina et al. 2014). Recognition and reconciliation therapy actions are necessary to reduce potentially inappropriate prescriptions, to decrease the risk of adverse drug reactions, to simplify and communicate the pharmacological regimen and to keep the person in control and involved in decision-making processes. Active collaboration and networking between patients, relatives, general practitioners, pharmacists, ward doctors and nurses, and pharmacologists is necessary to create and disseminate information for more effective care. Creating, or rather structuring and coordinating, already existing communities of practice, which necessarily share an interest in their own and others' care processes, is a necessary perspective for defining strategies and mechanisms for social innovation in the transition of care.

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