A Textbook of Clinical Pharmacy

for Pharmacy Students

Lesson 1:

Clinical Pharmacy

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Contents

1.1 About this chapter

Clinical pharmacy has emerged over the 70 years as a central pillar of patient-centered pharmacist care, and this chapter is intended to provide 4th year pharmacy students with a conceptual and historical foundation for understanding that role. As students transition from predominantly product- and systems-oriented training to direct involvement in **patient care**, it becomes essential to clarify what distinguishes clinical pharmacy from other areas of pharmacy, how it has evolved, and why it is now integral to modern health care delivery. The chapter therefore aims to frame clinical pharmacy both as an academic discipline and as a practical, **outcome-oriented** activity embedded in **multidisciplinary teams**.

A first rationale for the chapter is to make explicit the shift from a product-centered to a patient-centered paradigm in pharmacy, a shift that underpins nearly all subsequent topics in clinical pharmacy education. Historically, hospital and community pharmacists were mainly responsible for procuring, preparing and dispensing medicines, with limited systematic involvement in clinical decision-making at the bedside. The development of clinical pharmacy in the second half of the twentieth century reoriented pharmacists toward direct responsibility for the optimization of individual patients' pharmacotherapy, active pursuit of improved clinical outcomes. Understanding this change in paradigm helps students appreciate why activities such as **medication review**, participation in **ward rounds**, **therapeutic drug monitoring**, and **collaborative prescribing** have become core expectations rather than optional add-ons. [N.B., several of these services will be further explored in the Pharmaceutical Care course, next semester].

A second rationale is to introduce and critically examine key definitions and concepts that will recur throughout the reference book. At the same time, professional bodies and reference works have proposed definitions of clinical pharmacy that emphasize its scientific basis, its focus on the rational and evidence-based use of medicines, and its operationalization through specific clinical activities in different care settings. This chapter will present and contrast these definitions, discuss areas of overlap and divergence, and position clinical pharmacy within the

broader family of pharmacy practice disciplines, setting terminological clarity for the rest of the book.

A third reason for including an introductory chapter is to provide a concise historical narrative that explains how clinical pharmacy developed, first in a few pioneering institutions and then globally. Milestones such as the decentralization of hospital pharmacists to clinical wards, the creation of drug information centers, the advent of unit dose systems and ward-based clinical services, and the formalization of postgraduate clinical pharmacy training illustrate how structural changes in health systems enabled new professional roles for pharmacists. By briefly tracing these developments in North America, Europe and other regions, the chapter will help students understand why clinical pharmacy is more advanced in some countries than others, why models of practice differ, and how local implementation is shaped by regulation, education and health-system organization.

A further objective is to delineate the scope of contemporary clinical pharmacy practice across settings and to show how it interfaces with the specific topics covered in later chapters. **Modern clinical pharmacy encompasses activities in acute hospitals, ambulatory clinics, community pharmacy, primary care and long-term care facilities, and increasingly extends into public health and population-level medicines optimization**. Within these settings, clinical pharmacists contribute to medication reconciliation and review, identification and management of adverse drug reactions, antimicrobial stewardship, optimization of therapy in special populations (such as patients with renal or hepatic impairment, extremes of body weight, or advanced age), palliative care, pain management, and the integration of pharmacogenomic information into prescribing.

Finally, the chapter will underline why an understanding of clinical pharmacy is crucial for the future professional identity of pharmacy graduates and for the evolution of health systems. Health care is increasingly characterized by multimorbidity, polypharmacy, constrained resources and a demand for demonstrable value in interventions, all of which create a need for professionals skilled in optimizing complex pharmacotherapy in complex patients. Clinical pharmacy provides a structured approach to improving the safety, effectiveness and cost-effectiveness of medication use, and there is growing evidence that clinical pharmacy services can reduce medication errors, prevent adverse drug events and improve disease control in various conditions. By the end of the chapter, students should recognize clinical pharmacy not merely as a subspecialty but as a central, evidence-informed component of professional practice of pharmacy that supports rational pharmacotherapy at the level of the individual patient.

1.2 Historical Evolution of Clinical Pharmacy

1.2.1 Pre-clinical pharmacy times

The historical evolution of clinical pharmacy can be presented as a gradual but profound transformation from product-centered, logistics-oriented pharmacy towards a patient-centered clinical discipline integrated into health care teams. This trajectory spans developments in hospital and community pharmacy, and changes in education and regulation.

Early in the twentieth century, practice of pharmacy in hospitals and the community was largely focused on compounding, procurement, distribution and basic quality assurance of medicines, with minimal formal involvement in therapeutic decision-making or direct patient care. The pharmacist's work was typically confined to the dispensary and interactions with prescribers and patients were often limited to technical verification of prescriptions and provision of basic instructions for use. Although individual pharmacists might informally advise physicians, there was no systematic expectation that pharmacists would participate in clinical rounds or influence pharmacotherapy at the bedside.

APhA Code of Ethics, 1922–1969

The American Pharmaceutical Association (APhA) Code of Ethics adopted in 1922 and maintained in substantially similar form in the 1952 version, codified a very restrictive view of the pharmacist's relationship with patients and prescribers. One of its most cited clauses stated that: "**[The pharmacist] should never discuss the therapeutic effect of a Physician's prescription with a patron nor disclose details of composition which the Physician has withheld, suggesting to the patient that such details can be properly discussed with the prescriber only**". This single sentence encapsulated a hierarchical model of care in which the physician was the sole legitimate source of therapeutic information for the patient, while the pharmacist's role was confined to compounding and dispensing in strict deference to medical authority.

Within this ethical framework, any attempt by the pharmacist to explain the indication, expected effects, or alternatives of a prescribed medicine to the "patron" could be interpreted as an unethical intrusion into the physician–patient relationship. Historical analyses of community pharmacy practice in the United States indicate that, in line with this code, **prescription labels frequently omitted the name of the medicine**, and **pharmacists were discouraged from revealing the identity of the product if the physician had not done so**, further limiting opportunities for patient counselling. The pharmacist's professional loyalty was directed primarily towards the prescriber: questions about symptoms, diagnosis or treatment were to be redirected to the physician, and discussion of therapy with the patient was explicitly proscribed unless clearly authorized by the prescriber.

The later revision of the APhA Code of Ethics in 1969, which placed the health and safety of patients at the center of the pharmacist's obligations, can be interpreted as a deliberate departure from this earlier model and as a necessary ethical precondition for the subsequent development of clinical pharmacy as a patient-centered discipline.

- Urick BY, Meggs EV. Towards a Greater Professional Standing: Evolution of Pharmacy Practice and Education, 1920-2020. Pharmacy (Basel). 2019;7(3):98.

1.2.2 The Clinical Pharmacy pioneers (1950s–1980s)

Between 1950 and 1980, clinical pharmacy emerged from a few pioneering hospital initiatives in the United States that explicitly moved pharmacists from the central dispensary to the patient care areas and created new structures for medicines information. In this period, two developments were particularly influential: the establishment of early **drug information centers** and the introduction of **decentralized, ward-based clinical services** in teaching hospitals.

One of the earliest and most cited examples of organized medicines information activity is the **drug information center developed at University of Kentucky Albert B. Chandler Medical Center** in the mid-1950s, which provided systematic responses to questions from physicians and other health professionals about drug therapy, dosing, interactions and adverse effects. This center formalized the role of pharmacists as medication information specialists, using the emerging primary literature as well as reference compendia to support prescribing decisions rather than merely supplying products. The Kentucky experience showed that a pharmacist-run drug information service could become an integral part of hospital decision-making, and similar centers were soon developed in other academic medical centers, often in close connection with residency training programs in hospital and clinical pharmacy.

The University of Kentucky Drug Information Center

The University of Kentucky Drug Information Center (DIC) is widely regarded as one of the first formal drug information centers integrated into routine hospital practice in the United States. Established within the University of Kentucky Albert B. Chandler Medical Center, its primary purpose was to provide prompt, documented, responses to medication-related questions from physicians, nurses, pharmacists and other health professionals. The center was staffed by pharmacists with access to a comprehensive collection of reference books, journals and manufacturer data, and it used systematic search and documentation procedures that were innovative for their time.

Parker's emphasized that requests to the DIC covered a broad range of topics, including comparative efficacy and safety of medicines, appropriate dosing in special populations, drug interactions, compatibility of intravenous admixtures and interpretation of emerging clinical trial data. Questions were received mainly by telephone, and each answer was documented with a written record citing the sources consulted, creating an early model of traceable, accountable medicines information practice. The Kentucky DIC also provided educational outreach by feeding back recurrent or particularly important questions into teaching sessions for medical and pharmacy staff, thereby linking day-to-day information needs with ongoing professional education.

- Parker PF. The University of Kentucky Drug Information Center. Am J Hosp Pharm 1962;22(1):42-47

In parallel, pioneering hospital pharmacists in the 1950s and 1960s began decentralizing services to patient care units and participating directly in clinical activities. Narrative accounts describe pharmacists leaving the basement dispensary to establish **satellite pharmacies in wards**, where they managed unit-dose distribution systems and prepared sterile admixtures, especially for intravenous therapy. A landmark example from this era is the Ninth Floor Project at the University of California, San Francisco, which established a ward-based satellite pharmacy providing unit-dose dispensing, intravenous admixture services and on-the-spot drug information, with pharmacists readily available to answer clinical questions from physicians and nurses. These experiments demonstrated that pharmacists positioned on the wards could detect and resolve prescribing problems more effectively, adjust doses in response to renal function and other patient variables, and contribute to the safe and rational use of increasingly complex medicines.

The Ninth Floor Pharmacy Project at UCSF

The Ninth Floor Pharmacy Project at the University of California, San Francisco (UCSF) Medical Center is widely recognized as a seminal experiment in **decentralized hospital pharmacy** and clinical pharmacy practice. Planning began in 1965, when leaders of the UCSF School of Pharmacy and the medical center sought to create a "real-world laboratory" on the surgical ward of Moffitt Hospital in which pharmacists would assume expanded responsibilities in direct patient care. After months of preparation, the satellite pharmacy on the ninth floor opened on 7 September 1966 with the explicit goals of developing a ward-based pharmaceutical service to ensure maximum safe drug use, **charging the pharmacist with responsibility for all phases of drug distribution except administration**, and providing an easily accessible, unbiased source of drug information to the clinical team.

In this model, pharmacists received all medication orders on the ward, dispensed unit-dose medications, prepared intravenous additives, supervised technicians, and acted as the first point of contact for physicians' and nurses' drug-related questions. Reports from the project describe how, once the logistics of unit-dose distribution were stabilized, pharmacists increasingly joined teaching and work rounds, responded to cardiac arrest ("Code Blue") calls, provided in-service education to nursing staff, and taught pharmacy students and residents, thereby embedding pharmaceutical expertise directly into multidisciplinary care. Early evaluations indicated that the presence of pharmacists on the ward improved turnaround times for medication orders and was valued by surgical and nursing staff, who viewed the pharmacist as a full member of the patient care team.

The Ninth Floor Project also stimulated the development of a formal Drug Information Service at UCSF in 1968, initially staffed by the ninth-floor pharmacists and later by dedicated personnel, to handle increasingly complex and urgent literature-based queries from within the hospital and from the wider medical community. Experience from the project informed a radical revision of the UCSF pharmacy curriculum in 1969 and underpinned the establishment of a dedicated Division of Clinical Pharmacy in the early 1970s, with clinical services expanding from the original surgical floor to multiple inpatient and ambulatory care units.

- Smith WE, de Leon RF, Herfindal ET, et al. The Ninth-Floor Pharmacy Project at the University of California, San Francisco: A seminal development in clinical pharmacy. Am J Health Syst Pharm. 2015;72(23):2108-2113.

By the late 1960s and 1970s, these early models had stimulated wider changes in hospital pharmacy across the United States. **Unit-dose systems**, **pharmacist-managed IV admixture** services and formal **drug information centers** became reference standards in teaching hospitals, and **pharmacists increasingly joined ward rounds**, particularly in intensive care, oncology and other high-risk areas. The same period saw the growth of postgraduate hospital pharmacy residencies and early clinical pharmacy training, which were often organized around these decentralized services and information centers, creating a cadre of pharmacists whose primary identity was clinical rather than purely distributive.

Therapeutic drug monitoring (TDM) also played an important role in the evolution of clinical pharmacy, because it provided an early, concrete example of how pharmacists' pharmacokinetic and pharmacodynamic expertise could be applied directly to individual patients. From the 1970s onwards, TDM was increasingly used for medicines with narrow therapeutic indices and high interindividual variability, such as aminoglycosides, vancomycin, phenytoin, digoxin and some immunosuppressants, and pharmacists became key professionals in designing sampling strategies, interpreting serum concentrations and translating these data into dosage recommendations.[1] Reviews of the development of clinical pharmacy frequently highlight TDM services as one of the first structured clinical activities that required pharmacists to integrate laboratory data, renal and hepatic function, comorbidities and concomitant therapy to individualize dosing, rather than simply verifying that a prescribed dose was within a usual range. Over time, the establishment of TDM services in hospitals was associated with improved attainment of target concentrations and reductions in toxicity for several drug classes, and these outcomes helped legitimize the presence of pharmacists on wards and in multidisciplinary teams as clinicians whose interventions had measurable effects on patient safety and effectiveness of therapy. TDM is further explored in therapeutic drug monitoring course (4th year).

1.2.3 Modern Clinical Pharmacy

From the 1990s to the present, clinical pharmacy has entered what many authors describe as a consolidation and diversification phase, in which earlier hospital-based innovations have spread across sectors and become embedded in professional standards, education and policy. **Clinical pharmacy is now explicitly framed as a patient-centered, outcomes-oriented practice that should be present wherever medicines are used, including hospitals, ambulatory clinics, community pharmacies, primary care and long-term care facilities**.

In parallel, pharmacy education underwent profound change, particularly in North America and later in other regions, to support clinical roles. In the United States, the transition to the Doctor of Pharmacy (PharmD) as the single entry-level degree was completed in the early 2000s, accompanied by growth in postgraduate residencies and fellowships emphasizing direct patient care. European and international frameworks, such as those developed by the European Society of Clinical Pharmacy (ESCP), the European Association of Hospital Pharmacists (EAHP) and the International Pharmaceutical Federation (FIP), have defined competency sets for clinical pharmacists that explicitly include patient assessment, therapeutic decision-making, interprofessional communication and quality improvement. These frameworks emphasize that clinical competence is required in all care settings where patients use medicines, not only in specialized hospital units. More recently, European Union Directive 2024/782 included Clinical Pharmacy as one of the **minimum training requirements for the professions of the pharmacist**.

In hospitals, clinical pharmacy services have become progressively more structured and evidence-driven. Systematic reviews and practice guidelines describe a range of activities that are now considered core: participation in ward rounds; medication reconciliation at transitions of care; comprehensive medication review in high-risk patients; therapeutic drug monitoring and pharmacokinetic dosing; involvement in antimicrobial stewardship and infection control; and participation in formulary management and guideline implementation. There is growing evidence

[1] Kang JS, Lee MH. Overview of therapeutic drug monitoring. Korean J Intern Med. 2009;24(1):1-10.

that such services can improve surrogate and clinical outcomes, including reductions in potentially inappropriate prescribing, adverse drug events, drug-related hospital readmissions and, in some contexts, mortality and costs. Accreditation bodies and professional societies increasingly view these activities as essential components of high-quality hospital care rather than optional innovations.

Perhaps the most distinctive feature of the modern era, however, is the insistence that clinical pharmacy should not be confined to hospitals. FIP, ESCP, and national associations repeatedly stress that **clinical pharmacy principles apply equally in ambulatory care, community pharmacy and primary care settings**, where most medicines are prescribed and used. In primary care and outpatient clinics, clinical pharmacists have become key members of multidisciplinary teams managing chronic diseases such as diabetes, hypertension, heart failure, asthma and chronic obstructive pulmonary disease, often under collaborative practice agreements that authorize them to initiate, adjust or discontinue therapy within agreed protocols. Studies show that pharmacist-led clinics and collaborative care models can improve disease control, adherence and guideline concordance compared with usual care.

1.3 Concepts in Clinical Pharmacy

1.3.1 Defining Clinical Pharmacy

Clinical pharmacy is a term that has been defined and refined over several decades by professional associations and academic authors, and a clear understanding of its meaning is essential before discussing its practice. One of the most influential contemporary formulations is the definition endorsed by the **American College of Clinical Pharmacy** (ACCP)[2], which states that "**clinical pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention**". This definition explicitly presents clinical pharmacy as both a science and a practice: it is rooted in pharmacology, pharmacokinetics, therapeutics and outcomes research, but it is realized through the direct care of individual patients. Importantly, the ACCP text emphasizes that clinical pharmacists care for patients in all settings, including hospitals, clinics, community pharmacies, long-term care facilities and patients' homes, thereby rejecting any restriction of clinical pharmacy to hospital practice alone.

European organizations have converged on similar but not identical formulations. The **European Society of Clinical Pharmacy** (ESCP)[3] has described that "**Clinical pharmacy aims to optimise the utilisation of medicines through practice and research in order to achieve person-centered and public health goals**". The **European Association of Hospital Pharmacists** (EAHP)[4], while primarily hospital-oriented, have a dedicated section of the EAHP European Statements of Hospital Pharmacy, Section 4: Clinical Pharmacy Services, with 8 statements finishing with "Clinical pharmacy services should continuously evolve to optimise patients' outcomes". These definitions reinforce the idea that clinical pharmacy is characterized by a

[2] American College of Clinical Pharmacy. The Definition of Clinical Pharmacy. Pharmacotherapy 2008;28(6):816–817
[3] Dreischulte T, van den Bemt B, Steurbaut S; European Society of Clinical Pharmacy. European Society of Clinical Pharmacy definition of the term clinical pharmacy and its relationship to pharmaceutical care: a position paper. Int J Clin Pharm. 2022;44(4):837-842.
[4] The European Statements of Hospital Pharmacy. Eur J Hosp Pharm 2014;21:256–258.

systematic, patient-specific evaluation of pharmacotherapy embedded in clinical decision-making.

The Joint FIP/WHO[5] Guidelines on Good Pharmacy Practice (GPP) define four global roles for pharmacists, one of which is to "provide effective medication therapy management", including monitoring medicines for safety and effectiveness, identifying and preventing medication-related problems, and collaborating with other professionals in the direct care of patients. Although the guidelines do not label this role "clinical pharmacy", they describe functions that many national and regional bodies explicitly classify as clinical pharmacy services: medication review, reconciliation at transitions of care, ongoing monitoring of therapy, provision of medicines information, and participation in multidisciplinary decision-making about pharmacotherapy. In this sense, FIP's GPP document provides a global policy frame in which the clinical dimension of pharmacy is defined functionally, through responsibilities for **optimizing the safe and rational use of medicines for individual patien**ts, rather than through a single formal sentence using the term "clinical pharmacy".

Taken together, these various definitions allow a synthetic, working description suitable for pharmacy students. **Clinical pharmacy can be understood as the health science and professional practice in which pharmacists use their specialized knowledge of medicines and clinical sciences to provide direct care to patients, with the goal of optimizing medication therapy and improving health outcomes in collaboration with other health professionals**. Several features of this description deserve emphasis.

- First, clinical pharmacy is explicitly patient-centered: its primary unit of concern is the individual patient's pharmacotherapy, not the stock of medicines or the efficiency of the distribution system, even though clinical pharmacists may also contribute to system-level decisions.
- Second, clinical pharmacy is intrinsically clinical: it requires engagement with diagnoses, symptoms, laboratory data, comorbidities and other clinical information to judge the appropriateness, effectiveness and safety of medicines.
- Third, clinical pharmacy focusses the aims of its practice in patient's outcomes, mainly clinical but also economic and humanistic, rather than in process surrogate elements like adherence, knowledge or literacy.
- Fourth, clinical pharmacy is collaborative: it is practiced within multidisciplinary teams in which the pharmacist's expertise complements that of physicians, nurses and other professionals.

[5] FIP/WHO. Guidelines on Good Pharmacy Practice. https://www.fip.org/files/fip/WHO/GPP%20guidelines%20FIP%20publication_final.pdf

Clinical pharmacy definition (for FFUP students' purposes)

Clinical pharmacy can be understood as the health science and professional practice in which pharmacists use their specialized knowledge of medicines and clinical sciences to provide direct care to patients, with the goal of optimizing medication therapy and improving health outcomes in collaboration with other health professionals

1.3.2 Differences between Clinical Pharmacy and Pharmaceutical Care

Pharmaceutical care and **Clinical Pharmacy** are closely related but not interchangeable concepts.[6],[7] Clinical Pharmacy is primarily a health science discipline and a field of professional practice that develops the clinical knowledge, methods and evaluative framework for rational, patient-centered use of medicines, whereas Pharmaceutical Care is presented as the practice model and set of structured professional services through which that clinical knowledge is applied in day-to-day care.

In contemporary international definitions, clinical pharmacy integrates pharmacology, pharmacokinetics, therapeutics and outcomes research with direct patient care in all settings. Pharmaceutical care, in contrast, has been classically defined since Hepler and Strand as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life", a definition that was later operationalized by Cipolle, Strand and Morley as a patient-centered practice in which the pharmacist assumes responsibility for a patient's drug-related needs and is held accountable for this commitment. Pharmaceutical Care is therefore understood as the organizational and ethical framework within which pharmacists deliver specific services such as pharmacotherapy follow-up, medication management clinics or disease-specific programs, using the clinical reasoning and tools developed in clinical pharmacy to design, implement and monitor individualized care plans.[8]

From this perspective, one can say that Clinical Pharmacy asks and answers questions about what should be done with medicines from a clinical and scientific point of view, while Pharmaceutical Care structures how these decisions are implemented, documented and

[6] Ahmed SI, Hasan SS, Hassali MA. Clinical pharmacy and pharmaceutical care: a need to homogenize the concepts. Am J Pharm Educ. 2010;74(10):193g.
[7] Dreischulte T, Fernandez-Llimos F. Current perceptions of the term Clinical Pharmacy and its relationship to Pharmaceutical Care: a survey of members of the European Society of Clinical Pharmacy. Int J Clin Pharm. 2016;38(6):1445-1456.
[8] Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990;47(3):533-543.

followed up with individual patients over time. Clinical pharmacy encompasses not only direct patient care but also contributes to guideline development, formulary decisions, protocol design, and outcomes research, thus shaping the evidence base and professional standards for medication use at both individual and population levels. Pharmaceutical care, by contrast, is more focused on the continuous care process with a given patient or patient group: establishing a therapeutic relationship, assessing drug-related needs, agreeing goals of therapy, and conducting systematic follow-up to verify that agreed, patient-relevant outcomes are achieved. In practical terms, the services taught later in the 5th year Pharmaceutical Care course (e.g., medication review in polypharmacy patients, or medication follow-up in chronic disease) can be viewed as concrete applications of clinical pharmacy principles within a pharmaceutical care practice model, making the two concepts complementary but conceptually distinct.

1.3.3 Defining patient-centered care and shared decision-making

The Institute of Medicine has defined **patient-centered care** as "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions". Subsequent conceptual work has refined this to emphasize care that honors and responds to each patient's preferences, needs, values and goals, positioning the patient as an active partner rather than a passive recipient of treatment. In pharmacotherapy, this implies that choices about starting, continuing, adjusting or discontinuing medicines must consider not only biomedical evidence but also the patient's lived experience of illness, attitudes to medicines, daily routines and priorities.

Shared decision-making provides a concrete model for operationalizing patient-centered care in medication use. It is commonly defined as a collaborative process in which clinicians and patients make treatment decisions together, combining the clinician's expertise about diseases and therapeutic options with the patient's expertise about personal values, preferences and circumstances. In this model, clinicians are responsible for presenting the best available evidence on the benefits, risks and uncertainties of different medication options, while patients articulate what outcomes matter most to them and how they weigh potential trade-offs. A decision is considered "shared" when it is informed by evidence, aligned with the individual patient's preferences, and jointly agreed upon, rather than simply accepted or acquiesced to.

In the specific context of pharmacotherapy, shared decision-making has been applied to decisions about initiating or changing long-term medicines, choosing between drugs with different profiles of benefit and harm, and considering deprescribing when the perceived burden of treatment outweighs the benefits. Reviews of patient-centered interventions in medication management highlight several practical components: exploring the patient's understanding and beliefs about their medicines, using structured tools or decision aids to present options, discussing how each option fits with the patient's goals and daily life, and documenting the agreed plan in a way that supports follow-up and adherence. For clinical pharmacists, this means that activities such as medication review, counselling and monitoring should be conducted as dialogues in which patient goals and preferences are systematically elicited and used to guide recommendations, rather than as one-way transfers of information.

Although patient-centered care and shared decision-making are widely endorsed, their implementation in pharmacotherapy is not without problems and limitations. One persistent tension relates to situations in which the option most strongly supported by evidence does not

align with the patient's stated preferences or willingness to take medicines. Studies of shared decision-making around psychotropic and cardiovascular drugs, for example, show that some patients decline or discontinue pharmacotherapy that would be expected to reduce relapse or cardiovascular risk, often because of fears about adverse effects, stigma, or a desire to minimize pharmaceutical "burden". Clinicians then face the challenge of respecting autonomy while feeling responsible for the foreseeable consequences of untreated or suboptimally treated disease, and there is no simple algorithm for resolving this conflict.[9],[10],[11]

Operational constraints also limit what can realistically be achieved. Time-pressured consultations, fragmented care, and limited continuity make it difficult to elicit values and preferences in enough depth to support genuinely shared decisions about complex regimens, particularly in multimorbid patients with polypharmacy. In addition, **not all patients want the same degree of involvement at all times; some prefer clinicians to make strong recommendations, while others may experience detailed risk–benefit information as overwhelming or anxiety-provoking**.[12] There are further concerns about health literacy and power imbalances, as patients with lower literacy, language barriers or less confidence may agree to proposed plans without fully understanding options or feeling able to voice disagreement, resulting in a "pseudo-shared" decision that does not truly reflect their will. For clinical pharmacists, these limitations imply the need for careful judgement: striving to align therapy with each patient's preferences and goals, while also clearly communicating the likely clinical consequences of different choices and revisiting decisions as circumstances and patient views evolve.

1.3.4 Defining Interprofessional collaboration

Interprofessional collaboration in clinical pharmacy refers to the process by which pharmacists work together with physicians, nurses and other health professionals to plan, deliver and evaluate care, **sharing responsibility for patient outcomes** rather than operating in parallel silos. Conceptually, interprofessional collaboration is more than simple cooperation or referral; it involves mutual respect, clear role delineation, shared goals for the patient and regular, bidirectional communication about diagnosis, treatment and monitoring. In practice, this means that pharmacists contribute their expertise in pharmacotherapy and medication management within teams that also include medical, nursing and other professions, and that therapeutic decisions are made collectively, drawing on the complementary knowledge and skills of each professional.[13]

In the context of pharmacotherapy, interprofessional collaboration is operationalized through specific activities such as joint ward rounds, case conferences, multidisciplinary medication

[9] Stead U, Morant N, Ramon S. Shared decision-making in medication management: development of a training intervention. BJPsych Bull. 2017;41(4):221-227.
[10] Verwijmeren D, Grootens KP. Shared decision making in pharmacotherapy decisions, perceived by patients with bipolar disorder. Int J Bipolar Disord. 2018;6(1):21.
[11] Hopwood M. The Shared Decision-Making Process in the Pharmacological Management of Depression. Patient. 2020;13(1):23-30.
[12] Kuntz JL, Safford MM, Singh JA, et al. Patient-centered interventions to improve medication management and adherence: a qualitative review of research findings. Patient Educ Couns. 2014;97(3):310-326.
[13] Barnett NL. Opportunities for collaboration between pharmacists and clinical pharmacologists to support medicines optimisation in the UK. Br J Clin Pharmacol. 2019;85(8):1666-1669.

reviews, shared care protocols and collaborative practice agreements that authorize pharmacists to adjust therapy under defined conditions. For students, it is important to understand that interprofessional collaboration is not optional "goodwill" but a structural requirement for safe and effective use of medicines in modern health systems: no single professional can, alone, hold all the information and competencies needed to optimize pharmacotherapy in patients with multimorbidity and polypharmacy.

Recent work on community pharmacy and primary care integration conceptualizes "**integration**" as a structured, multi-level process through which community pharmacies become embedded components of primary health-care systems rather than parallel or peripheral providers. Integration is described along several dimensions: organizational (how services are arranged and governed), functional (how information and support systems are shared), clinical (how care processes are coordinated for individual patients) and normative (the extent to which professionals share values, vision and culture. From this perspective, an integrated model of care exists only when community pharmacy services are deliberately aligned with primary-care structures, with clear roles, shared objectives and mechanisms to coordinate pharmacotherapy for defined patient populations.[14],[15],[16]

1.3.5 Other relevant definitions: AE, ADR, ME, ADE

An **adverse event** refers to any problematic medical occurrence that happens during treatment with a medicinal product, regardless of whether it has a causal relationship with that treatment. In other words, an adverse event is something undesirable that occurs after taking a drug but is not necessarily caused by it. Examples include events such as a car accident, headache, or viral infection that happen during a clinical trial while the participant is on active therapy. These occurrences are temporally associated with the treatment but may be unrelated to the drug's pharmacological action. The International Conference on Harmonization (ICH E2D) and the WHO both define an adverse event as "**any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product**".

By contrast, an **adverse drug reaction** (ADR) is defined as a harmful and unintended response to a medicinal product that is causally related to its use. According to the WHO definition[17], an ADR is "**a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function**". The key determinant is the causal relationship between the drug and the event. If causality is established or reasonably suspected, the event is classified as an ADR. For example, a patient who develops a rash due to penicillin allergy

[14] Urionagüena A, Piquer-Martinez C, Benrimoj SI, et al. Mapping the concept of health care integration: A lexicographic analysis of scientific literature. Res Social Adm Pharm. 2024;20(5):506-511.
[15] Piquer-Martinez C, Urionagüena A, Benrimoj SI, et al. Integration of community pharmacy in primary health care: The challenge. Res Social Adm Pharm. 2022;18(8):3444-3447.
[16] Urionagüena A, Piquer-Martinez C, Gastelurrutia MÁ, et al. Community pharmacy and primary health care - Types of integration and their applicability: A narrative review. Res Social Adm Pharm. 2023;19(3):414-431.
[17] WHO. International Drug Monitoring: the role of national centers (1972). https://who-umc.org/media/2680/who-technical-report-498.pdf

experiences an ADR, whereas another patient who catches influenza while on penicillin experiences an adverse event.

A **medication error** is defined as **any preventable event that may cause or lead to inappropriate medication use or patient harm while the drug is under the control of a healthcare professional, patient, or consumer**. Errors can occur at any stage of the medication-use process (i.e., prescribing, transcribing, dispensing, preparation, administration, or monitoring), and may involve omissions, miscommunication, or incorrect execution of an intended action. These errors may be due to human factors such as misinterpretation, workflow pressures, or system design flaws. Importantly, **medication errors are not synonymous with harm**: many are intercepted before reaching the patient (so-called **near misses**), while others result in no clinical injury despite occurring.

An **adverse drug event** is a broader concept that encompasses any injury resulting from any intervention related to a drug. This includes both harm directly caused by a drug's pharmacologic activity (adverse drug reactions) and harm from errors in prescribing or administration, such as overdoses or incorrect routes of delivery. **All ADEs, by definition, involve patient harm, but not all are due to errors**.

All these concepts will be further explored in the Pharmacoepidemiology and Pharmacovigilance course (5th year).

1.3.6 Other relevant definitions: medication review, reconciliation, and follow-up

Medication review is a structured and systematic evaluation of a patient's complete medication regimen, with the explicit aim of optimizing medicines use. In widely adopted consensus definitions, medication review is not limited to a single prescription, but considers all prescribed, over-the-counter and, where relevant, herbal or complementary products, considering clinical status, laboratory data, comorbidities and patient preferences. Medication review is an intervention with demonstrated impact on the quality and safety of pharmacotherapy, particularly when it is patient-centered, iterative and embedded in interprofessional care. Studies and guidelines have linked well-conducted reviews to reductions in potentially inappropriate prescribing, improved alignment of therapy with renal and hepatic function, fewer preventable adverse drug events and, in some settings, reductions in drug-related hospitalizations and health-care costs. From an educational perspective, medication review serves as a practical framework through which pharmacy students learn to apply pharmacology, therapeutics and evidence-based medicine to real patients, moving from a product-focused to an outcome-oriented paradigm of practice.[18]

Medication reconciliation is a formal process designed to ensure the accuracy and continuity of the patient's medication regimen at transitions of care, by creating the most complete and accurate list possible of all medicines a patient is taking and comparing it with current medication orders. Authoritative bodies such as The Joint Commission and WHO define medication reconciliation as the systematic comparison of pre-admission (or pre-consultation) medicines with those prescribed at admission, transfer or discharge, with the goal of identifying and resolving unintended discrepancies such as omissions, duplications, dosing errors or

[18] Griese-Mammen N, Hersberger KE, Messerli M, et al. PCNE definition of medication review: reaching agreement. Int J Clin Pharm. 2018;40(5):1199-1208.

unintended drug interactions. The process typically includes obtaining a "best possible medication history" from multiple sources (patient, caregivers, previous records, community pharmacy), documenting it in a standardized form, comparing it with the new orders, clarifying any differences with prescribers, and communicating and documenting the reconciled regimen.[19] Evidence summarized in patient-safety reports indicates that failures in reconciliation at admission, internal transfer or discharge are a frequent source of preventable medication errors and adverse drug events, especially in older patients with polypharmacy and complex care pathways. Clinical pharmacists frequently lead or support reconciliation programs in hospitals and primary care, working with physicians and nurses to embed structured reconciliation steps in admission and discharge workflows, and to ensure that updated, comprehensible medication lists are communicated to patients and community providers.

Medication follow-up (often termed **pharmacotherapy follow-up**) refers to the ongoing, personalized professional practice in which the pharmacist assumes responsibility for the patient's needs related to medicines over time, with the aim of ensuring that pharmacotherapy is effective and safe in that specific individual. Unlike a single medication review episode, medication follow-up is conceived as an ongoing care process that accompanies the patient over successive encounters, integrating clinical monitoring, reassessment of therapy, reinforcement of adherence, patient education and adjustment of the care plan as the clinical situation evolves. Within the broader framework of pharmaceutical care and clinical pharmacy, medication follow-up can be viewed as the longitudinal "care model". Observational studies and implementation projects using structured methods such as the Dáder Program suggest that pharmacist-led medication follow-up in chronic diseases can improve control of clinical parameters.[20] Conceptually, medication follow-up operationalizes patient-centered care and shared decision-making by making the pharmacist's relationship with the patient continuous rather than episodic, and by explicitly aligning pharmacotherapy goals with the patient's values, preferences and evolving health status.

All these concepts will be further explored in the Pharmaceutical Care course (5th year).

1.3.7 Clinical Pharmacy and the term "drug-related problems"

Clinical pharmacy, understood as a clinical, outcome-oriented discipline embedded in multidisciplinary care, has strong reasons to move beyond the terminology of "drug-related problems". The classical definition of a drug-related problem[21] as "**an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes**" has been useful to structure pharmacists' thinking and classifications, but it remains terminologically ambiguous and poorly aligned with broader safety and outcomes frameworks.[22]

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[19] Pronovost P, Weast B, Schwarz M, et al. Medication reconciliation: a practical tool to reduce the risk of medication errors. J Crit Care. 2003;18(4):201-205.
[20] Martinez Romero F, Fernandez-Llimos F, Parras M, et al. Programa Dáder de Seguimiento del Tratamiento Farmacológico. Resultados de la fase piloto. Ars Pharm. 2001;42(1):53-65.
[21] Strand LM, Morley PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: their structure and function. DICP. 1990;24(11):1093-1097.
[22] Fernández-Llimós F, Tuneu L, Baena MI, Garcia-Delgado A, Faus MJ. Morbidity and mortality associated with pharmacotherapy. Evolution and current concept of drug-related problems. Curr Pharm Des. 2004;10(31):3947-3967.

In multidisciplinary environments, concepts such as “medication harm”, “adverse drug event”, or “medication-related harm” are far more frequently used and better understood.[23] Narrative reviews of medication harm terminology show a proliferation and overlap of terms (adverse drug event, adverse drug reaction, medication error, drug-related problem, medication-related problem, etc.), with inconsistent definitions and classifications that hinder comparison of data across settings and disciplines and complicate communication with regulators and policy-makers.

Moreover, “problem” is a vague and process-oriented label that mixes very heterogeneous phenomena (errors, risks, adherence issues, monitoring gaps) without explicitly stating whether the patient has suffered, or is likely to suffer, a health outcome that matters clinically.

A further argument for abandoning “drug-related problems” is the need for a terminology that is explicitly outcome-focused and compatible with international consensus efforts in medication safety and pharmaceutical care. The third Consensus of Granada[24] reframed the object of pharmaceutical care as “negative outcomes associated with medication”, defining these as health outcomes not consistent with the pharmacotherapy objectives and linked to the use or failure to use medicines, and classifying them in necessity, effectiveness and safety domains. This shift from “problems” to “negative outcomes” directs attention to the patient’s health state rather than to intermediate process deviations, and it allows quantitative measurement of impact in terms directly comparable with other clinical outcomes research. In parallel, works in medication safety and pharmacovigilance has emphasized the need for standard descriptors of medication-related harm across jurisdictions and systems, arguing that without uniform outcome-based terminology, it is difficult to quantify, compare or pool data on harms and to design effective quality-improvement interventions.

From this perspective, clinical pharmacy that aspires to function as a fully integrated clinical discipline should privilege terms that: align with multiprofessional usage, explicitly refer to patient-level health outcomes, and can be mapped to regulatory and safety taxonomies, rather than maintaining a profession-specific label such as “drug-related problems” that is ambiguous, process-centered and increasingly out of step with contemporary conceptualizations of medication-related risk and benefit.[25]

[23] Falconer N, Barras M, Martin J, Cottrell N. Defining and classifying terminology for medication harm: a call for consensus. Eur J Clin Pharmacol. 2019;75(2):137-145.
[24] Comité de Consenso. Tercer Consenso de Granada sobre Problemas Relacionados con Medicamentos y Resultados Negativos asociados a la Medicación. Ars Pharm. 2007;48:5–17.
[25] Fernandez-Llimos F, Faus MJ. From "drug-related problems" to "negative clinical outcomes". Am J Health Syst Pharm. 2005;62(22):2348-2350.