

# ENSURING PATIENTS' SAFETY IN DRUG THERAPY THROUGH PHARMACEUTICAL CARE

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## INTRODUCTION

The dynamics of ensuring patient's safety in drug therapy is as old as the profession of pharmacy itself. The dynamic profession of pharmacy has undergone series of changes in terms of philosophy and practice as it seeks to meet the dynamics of societal expectations, changes in the legal regulatory standards as well as technology of health care provision to meet patient's expectations.

In the evolution of pharmacy, the profession has undergone changes occurring simultaneously across the globe (Nigeria should not be left out) from product to patient orientation.

Stages in the evolution of the profession from product to patient orientations are briefly presented.<sup>1</sup>

**Apothecary model**

**Compounding model**

**Distribution**

**Clinical Pharmacy model**

**Pharmaceutical care model**

In this presentation, 'Ensuring Patients' Safety in Drug Therapy would be discussed under:

- (i) Pharmaceutical Care
- (ii) Rational Drug Therapy
- (iii) Good Dispensing Practice

## PHARMACEUTICAL CARE

The philosophy of clinical or patient oriented pharmacy that emerged in the 1960s has metamorphosed to pharmaceutical care (patient focused). It is value added clinical pharmacy practice. This concept emerged in the 1990's and has gained global attention as a strategy to refocus the profession to meet the dynamic needs of the society in the area of optimization of drug therapy i.e to maximize the benefits and minimize the risk associated drug therapy. Pharmaceutical care seeks to achieve results where none exist or to improve on an existing one.

Pharmaceutical care is defined very simply as the process of finding and solving

(or avoiding) drug therapy problems, and some of the services include suggestion of drug and or non drug therapy as needed, referring the patient to another health care provider, patient education, and provision of disease state management services.

The International Pharmaceutical Federation 1998 statement describes pharmaceutical care as the responsible provision of pharmacotherapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It is a collaborative process that aims to prevent or identify and solve medicinal product and health related problems. This is a continuous quality improvement process for the use of medicinal products. The new role requires pharmacists to apply a higher level of drug knowledge, clinical skills and independent judgement to their work and to accept the burden of responsibility. Pharmaceutical care thus emphasizes the role of pharmacists in two broad areas: medicines management and health promotion.

Hepler and Strand (1990), defined pharmaceutical care as the responsible provision of drug therapy with goal of achieving definite outcomes that improve the quality of life of the patient.

From these definitions, it is clear that pharmaceutical care can be a philosophy, concept, process, service and even a tool in ensuring patients' safety in drug administration.

## Operational description of Pharmaceutical Care

We should understand pharmaceutical to mean the model of pharmacy practice wherein the pharmacist takes it upon himself to work with the patient and other caregivers to solve patients' drug and health related problems. Pharmaceutical care model has clearly defined what the pharmacist can do for a patient and how he does it. Practitioners focus on the patient and not the prescription or medication. Pharmaceutical care affects the way the pharmacists think and act in relation

to patients. Pharmaceutical care has become a dominant aspiration of pharmacy practice worldwide in the past decades and aims to improve patient outcomes: clinical/therapeutic, humanistic and economic.

**Outcomes of therapy:** Clinical/therapeutic, humanistic and economic outcomes.

**Clinical/Therapeutic Outcomes:** These may include: curing the patient; elimination or reduction of patient's symptoms; preventing or slowing the disease; prevention of disease or symptom; diagnosis of a disease; avoidance of drug related problems such as wrong indication, adverse drug reaction, non-compliance.

**Humanistic Outcomes:** These are the quality of life outcomes and they impact on the patient's physical, social and emotional well being as observed by the health care team. And more importantly patients own assessment of the impact of his/her quality of life. In the use of antihypertensive for instance, the twin goal is to lower blood pressure and prevent complications. However, the antihypertensives impact on the patient's quality of life which he may perceive more threatening than the beneficial effect of the antihypertensives. And in that case the patient might take responsibility not to comply with the medication. Such quality of the impact of antihypertensives include: reduction in sexual function, cognitive function: effects on sleep, mood and the general well being of the patient.

**Economic outcomes:** Drug therapy has financial implications both on the individual and the national economy. When the wrong drug is used it is a waste and when excess or under dose of the right drug is used, it is also wasteful. When a patient is given a drug he cannot afford his treatment is not optimized no matter how efficacious the drug is. In this instance the pharmacist in providing



pharmaceutical care brings to bear his **Drug Therapy Problems**

professional knowledge and responsibility in choosing an alternative drug or making generic substitution based on bioequivalence information.

A drug therapy problem is any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially

interferes with a desired patient outcome. The term is used to denote a drug-related event amenable to detection, treatment or prevention.

**Translating Drug-Related Needs into Drug Therapy Problems**

PATIENTS EXPRESSION	DRUG-RELATED NEEDS	DRUG THERAPY PROBLEMS
Understanding	Indication	1. Additional drug therapy
Expectations	Effectiveness	2. Unnecessary drug therapy
Concerns	Safety	3. Wrong drug
Behaviour	Compliance	4. Dosage too low
		5. Adverse drug reaction
		6. Dosage too high
		7. Compliance

These seven classes of drug related problems could be further reduced into four: Indication, Efficacy, Safety and Compliance. It must be remembered that Drug therapy related problems is the heart and soul of pharmaceutical care.

**Quality of Pharmaceutical Care**

The measures of quality in pharmaceutical care in line with Donabedian's model are the structure, process and outcome. The outcomes of drug therapy have already been discussed above.

**Structure Standards:** To provide pharmaceutical care some necessary structures are needed be it in the hospital or community pharmacy. Basic structures include: the layout of the pharmacy; presence of a counselling room; number of pharmacists; training of the pharmacist; availability of patient medication profile, drug use review protocols, pharmacy and therapeutic committee, etc.

**Process:** It includes detection of adverse drug reactions, counselling techniques, patient waiting time etc.

**Implementing the Pharmaceutical Care Process**

**Step 1:** Establishing some basic structure in the pharmacy that is different from what is used for traditional

Functions.

**Step 2:** Pharmacists overcoming the inertia of starting something new- acceptance of other health care workers, improving knowledge and skill.

**Step 3:** Establishing relationship with the patient by communicating the concept to the patient - their expectations and benefits i.e identity Mr. X as my hypertensive patient who I have outlined some pharmaceutical care plan for.

**Step 4:** Collection of patient centred information: demographic - many demographic attributes are factors in correct drug selection and usage and these include age, sex, occupation, level of education.

**Clinical Information:** Involves obtaining information pertinent to the patient's history such as current medication use, immunization history, allergies, psychosocial habits, name and address of other health care providers current medical problems etc. These could be obtained for your practice by patient/family interview, existing medical records etc.

**Physical Assessment:** Information can be obtained as needed but it should be noted that this is an area pharmacists need to improve upon. This information may be collected through record review or by performing an

actual physical assessment on the patient using the appropriate assessment skills such as blood glucose testing, blood pressure monitoring, cholesterol screening at your practice site, past medical records etc.

**Diagnosis Data:** This not only includes appropriate laboratory data to monitor the medical condition or drug therapy but also involves the pharmacist's understanding of the patients' knowledge of their disease states whether they know the risks associated with the disease and their importance/difference in untreated versus treated outcomes. Pharmacists should also obtain answers from patients to therapy questions such as "what do they do if they miss a dose"? "Do they know the appropriate storage for their drugs"? "Can they read their prescriptions"? "Do they understand the direction"? This information may be gathered by patient interview and existing medical record.

**Documentation of Activities:** In the pharmaceutical care process the slogan is - "if you don't write it you did not do it" and hence we must learn to document all pharmaceutical care activities. The provision of pharmaceutical care for a prolonged period of time requires a documentation system that adequately supports the practice. Such a system must generate three different types of output namely:



Pharmaceutical Care Patient Chart, The Patient's Personalized Pharmaceutical Plan and Management Reports.

Pharmaceutical Care Patient Chart is the most important of the three and pharmaceutical care cannot be provided without this chart. Although the chart is created on patient specific basis and for the practitioner's use, it is the source of document for other reports.

**Pharmaceutical Care in Selected Disease States:** The pharmaceutical care process is expensive in terms of personnel, materials, documentation, time, etc. and to be meaningful it must be focused since pharmaceutical care does not prevent the traditional dispensing role of the pharmacist, focus can be on chronic disease such as hypertension, diabetes mellitus, asthma, rheumatoid arthritis etc.

#### Case illustration with Hypertension

The role of the pharmacist in providing care to patients involves many components including the following: education of patients and family members about hypertension and medications especially its asymptomatic nature, chronicity and need for financial and emotional support; designing patient specific medication regimen; monitoring the individuals medication regimen for appropriateness of medication and doses over time; assessing compliance; intervening with creative approaches to improve adherence with the treatment regimen and screening for the development of adverse drug reactions and drug interactions, etc.

Drugs constitute an important and effective tool in the diagnosis, treatment, prevention of diseases and improvement of health.

The availability of effective drugs for the cure, prevention or alleviation of disease is a key factor in healthcare delivery.

Unfortunately, optimal benefits of the advances made in pharmaceutical care in the last couple of decades do not always accrue to the society.

This deficiency is global but assumes added significance in the developing countries because of inadequate training of healthcare professionals, poor economic and

social developments.

#### RATIONAL DRUG USE

A key factor in the failure of society to derive optimal benefits of the use of effective drugs is the issue of Rational Drug Use.

The requirements of rational drug use are that:

- \* right drugs are used for the right indication
- \* in the right dose and dosage form and
- \* for the right duration.

When these requirements are not met in the course of treatment, the use of drug is said not to be rational (or irrational).

#### THE PROCESS OF RATIONAL TREATMENT

Patients vary in age, gender, size and sociocultural characteristics, all of which may affect treatment choices.

Drug treatment should be chosen on the basis of:

- \* efficacy
- \* safety
- \* suitability
- \* cost

To achieve this, relevant information on the above items have to be obtained.

#### Efficacy

The efficacy of a drug is determined by its pharmacodynamic and pharmacokinetic profiles (e.g. development of tolerance, high first pass phenomena; varying absorption in the gastrointestinal tract).

By comparing the pharmacodynamic and the pharmacokinetic properties of the possible drugs to be used, information on their efficacies can be obtained.

#### Safe: possible side effects and toxic effects

All drugs groups have side effects, most of which are direct consequences of the mechanism of their actions.

Side effects are major problems in therapeutics. It is estimated that about 10% of hospital admissions are due to adverse drug reactions.

Unfortunately, not all drug-induced adverse effects can be prevented but those caused by inappropriate selection of dosage can be prevented.

Appropriate care should be exercised for high risk groups, such as:

- \* the elderly
- \* children
- \* pregnant women
- \* patients with kidneys or liver disease

From published data about the drugs, the relative safety can be evaluated.

#### Suitability

The suitability of a drug usually concerns an individual patient. However, some general aspects of suitability can be considered when a choice of drug is being made. Contraindications are related to patient conditions, such as:

- \* illnesses which make it impossible to use a particular drug that is otherwise effective and safe
- \* a change in the physiology of the patient that may influence the dynamics or kinetics of a drug, resulting in sub therapeutic blood levels or toxic side effects occurring at normal blood concentrations.
- \* in pregnant or lactating patients
- \* interaction with food or other drugs can reduce or increase the effect of the drug
- \* convenient (or inconvenient) dosage form or dosage schedule can influence patient compliance.

#### Cost of Treatment

The cost of treatment is an important factor in selecting a drug in both developed and developing countries. This criterion assumes added significance in situations of limited resources, non-availability of well organised general healthcare, health insurance or reimbursable health costs.

The ideal choice in terms of efficacy and safety may also be the most expensive drug and in case of limited resources, this may not be suitable.

Sometimes, a choice has to be made between treating a small number of patients with a very expensive drug, and treating a much larger number of patients with a drug which is less ideal but still acceptable.

When too many drugs are prescribed, the patient may not purchase some of them, or inadequate quantities.

In situations where cost is an important constraint, only drugs that are really necessary should be selected.



The total cost of treatment rather than the cost per unit drug should always be considered.

### RATIONAL PRESCRIBING

Rational prescribing involves:

- \* the right drug
- \* at the right time
- \* in the right dose of the right formation
- \* for the right length of time
- \* not prescribing any drug at all if no prescription is called for.

Irrational drug prescribing can occur when the prescribed drug is:

- \* incorrect
- \* inappropriate
- \* excessive
- \* unnecessary or
- \* inadequate

Examples of irrational prescribing include:

a) Incorrect Prescribing: wrong drug is prescribed

- \* when there is a safer and more effective drug
- \* incorrect route of administration

b) Inappropriate Prescribing: the most appropriate drug is not prescribed

- \* unusual or rarely stocked drug is prescribed when there is a clinically equivalent drug that is readily available
- \* expensive drug is prescribed when a less expensive but equally safe and effective one is available

\* prescribing an expensive branded drug when less expensive generic is available

- \* prescribing drugs whose safe and effective use require monitoring with facilities that are not readily available.

c) Over Prescribing

- \* drug is not needed
- \* dose is too large
- \* quantity prescribed is excessive for the course of treatment

- \* the duration of treatment is too long

d) Multiple Prescribing: an unnecessary large number of drugs are prescribed

e) Under Prescribing: inadequate amount of drug is prescribed

- \* inadequate dose
- \* duration of therapy too short

### GOOD DISPENSING PRACTICE

The concept "good dispensing practice" is a quality assurance tool in the drug utilization process. The aim is to ensure that

the right patient receives the appropriate medicine in the correct dose and form with the adequate instruction on its usage. The practice of dispensing medications is a core pharmacy function irrespective of whether it is product or patient oriented pharmacy practice. In patient-oriented pharmacy practice, the pharmacist is involved in both distribution of the core product (drug) and information distribution (the extended product);

Good dispensing practice may therefore be conceptualized as a standard dispensing function. The following steps should be covered and systematically audited when dispensing medication:

1. Prescription validation (verification)
2. Product selection
3. Choice of suitable container
4. Labelling
5. Patient counselling
6. Record keeping (documentation)

#### Prescription Validation (Verification)

The pharmacist has a professional and legal responsibility to question and verify all prescription for legality (contains the name, age, sex, and address of the patient as well as the name, signature and code of the prescriber on the approved prescription format or an institution), correctness, completeness, potential drug interactions and patient allergies, before they are dispensed.

Prescription validation entails effective communication with the prescriber, the patient and reliable drug information source/good clinical judgement.

#### Product Selection

When a prescription is for a branded product the only decision is to ensure that the correct brand is used. But often times, prescription can come in generic name, which poses the question of brand selection and generic substitution with the attendant issue of bioequivalence and therapeutic equivalence. In deciding on a brand to use, the following concepts should be noted:

- Pharmaceutical alternatives - contain the same therapeutic moiety but differ in chemical form (salt or esters) of the moiety or in the dosage form or strength, chloroquine phosphate tablets and chloroquine sulphate tablets are pharmaceutical alternatives.

- Pharmaceutical equivalents (chemical equivalents) - contain the same amount of the same active substance in the same dosage form that meet the corresponding standards.

- Bioequivalent - pharmaceutical equivalents or alternatives that have comparable bioavailability (rate and extent of drug absorption).

- Therapeutic equivalent - bioequivalent products with comparable efficacy and adverse effects.

- Generic prescribing and dispensing ensure drug availability and cost reduction. However, because our national drug laws do not make for mandatory comparative bioavailability with innovator product, generic substitution should be used with caution. Bioequivalence is the only rational basis for generic substitution in good dispensing practice. The following recommendations should be considered:

- \* severe medical condition: use reputable brands.

- \* mild conditions: preferable a known brand or generic

- \* drugs with narrow therapeutic index e.g digoxin, warfarin - no generic substitution.

- \* drugs with erratic absorption e.g phenytoin, no generic substitution.

- \* patient stabilized on given brand or generic for a chronic condition - should be maintained on the brand/generic.

#### Choice of Suitable Container

The container should preserve the integrity of the product from factors of moisture, light etc.

Tablets/capsules are dispensed in:

Step 1 (minimum requirement) - an airtight plastic wallet.

Step 2 an airtight, rigid container

Step 3 (Optimal requirement) - an airtight rigid container with a child resistant closure. The container must be opaque when drug is photosensitive (methyldopa, nifedipine, chlorpromazine etc).

Step 4 (ideal condition) - the manufacture's original pack.

Liquid preparations should be dispensed in pharmaceutical bottles so as to differentiate



them from non-pharmaceutical preparations. Poisonous product/products intended for external use should be packed in distinguishable bottles, (preferably ribbed bottles). This also helps the visually impaired patient to distinguish between drugs for internal use and those for external applications.

### Labelling

Drug label is made up of primary label, which contains clear, concise and comprehensive instructions to patients, and auxiliary/cautionary label, which reinforces or supplements primary label. The minimum requirements for a label are:

- \* Generic name and strength of medicine
- \* Dose frequency and duration of course (if applicable).
- \* Date of dispensing
- \* Name of patient (in full)
- \* Child safety warning

The instructions could be hand-written or printed/typed and affixed to the containers. Some recommended cautionary/advisory labels include:

- \* may cause drowsiness. If affected do not drive or operate machinery e.g antihistamines, sedatives hypnotics, etc.
- \* avoid alcoholic drinks e.g metronidazole, chlorpropamide, sedative, antipsychotics.
- \* take at regular intervals and complete the prescribed course unless otherwise directed e.g antibacterial agents.
- \* do not take on empty stomach - chloroquine, quinine, NSAIDs, doxycycline, metronidazole.
- \* Swallow whole not chewed - extended release and enteric-coated products.
- \* take an hour before food or on an empty stomach - ampicillin, tetracycline, halophantrine.

**Patient Counselling:** Counselling is a professional responsibility and not an option for the pharmacist and effective counselling skill must be acquired or developed to ensure good dispensing practice. Counselling is imperative because:

- \* Patients need to be motivated to take

their drugs.

- \* Many patients don't read label instructions.

- \* Advice on drugs are better appreciated if the drugs are before the patient and this places the pharmacist in a unique position to counsel since he has both the drug and the knowledge.

Pharmacist active involvement in patient counselling will improve compliance and the following areas should be covered:

- \* Name of the medication
- \* Indication in lay language e.g the medicine is for blood pressure
- \* Removal of medicine from pack - should be demonstrated e.g removal of suppository wrappings; opening of safety container, using cap to screw tubes and pressing of content from the base of collapsible tubes.
- \* Where and how to administer e.g do not chew, swallow with water.

Frequency and correct interval - use knowledge of pharmacokinetics to interpret interval e.g "qds" for tetracyclines need equal intervals (q6h) whereas "qds" for paracetamol needs four hours spacing i.e subject to a maximum of 4 does.

- \* Duration of use - when many drugs are dispensed the one that must be completed whether patient feels better or not must be specified.

- \* Side effects - to be tactfully communicated e.g metochlorpromide and rifampicin can colour urine, ferrous salt vitamin B complex, metronidazole can darken faeces; nifedipine can cause headache. Side effects that warrant medical attention should be pointed out from the ones the patient can manage.

- \* Contraindications - state food, drinks or drugs to be avoided.

- \* Allergies - when drugs with high incidence of allergy are dispensed, patient must be questioned e.g penicillins, sulfonamides and chloroquine.

- \* Storage/disposal of leftover drugs - patients should be discouraged from using

leftover drugs. The standard practice is to return them to the pharmacy for proper disposal.

### CONCLUSION

Ensuring patients' safety in drug therapy through pharmaceutical care should be the concern of everyone - pharmacists, other caregivers and even the patients.

Each time a drug is prescribed and administered to a patient, the patient automatically assumes a degree of risk that the drug may actually produce a harmful effect than beneficial one.

To this end, pharmaceutical care which helps to identify, prevent and resolve drug related problems is strongly advocated to improve patients' health.

Pharmaceutical care is dominating the pattern of pharmacy practice in many countries and Nigeria pharmacists should not be left out.

Pharmaceutical care is facilitated through acquisition of practice skills in health education, health promotion, communication skills, logical thinking, critical thinking, analytic thinking, problem solving and decision making.

Ensuring patients' safety in drug therapy through pharmaceutical care also requires that pharmacist develop adequate inter-professional relationship with other caregivers and the patients thus making the patient an active participant rather than a passive recipient in matters that affect drug safety.

Patients are ever becoming conscious of their right to quality products and services. Pharmaceutical care is thus well structured to provide and ensure these expectations. Pharmaceutical care therefore is their right. It is therefore the pharmacists' professional responsibility (not an option) to provide and ensure patients' safety in drug therapy through pharmaceutical care.

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