



INTRODUCTION TO OVER-THE- COUNTER DRUGS AND SELF-CARE

Course Name: over-the-counter drugs

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DEFINITION OF OVER-THE-COUNTER DRUGS (OTC)

- **FDA** defines OTC drugs as:
- *Safe and effective for use by the general public without a doctor's prescription.*
- <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#O>
- *Nonprescription medications, by definition, may be used **without** medical supervision.*
- *OTC= Nonprescription Medications*

NONPRESCRIPTION STATUS

- A drug can be marketed as a nonprescription product if it can be used by a consumer **guided by the product label** such that the consumer can self-diagnose, self-treat, and self-manage the condition requiring attention and if no health care provider is needed for the safe and effective use of the product.
- The drug also must have a **low potential for abuse and misuse**
- The **benefits** of nonprescription availability must **outweigh the risks**.
- *A state may not allow a prescription drug to be sold as other than prescribed, but a state may restrict a drug with nonprescription status under federal law to prescription status.*

PREScription-TO- NONPRESCRIPTION SWITCH

- ❖ Since the mid-1970s, FDA has switched more than 100 ingredients, dosages, or indications from prescription to nonprescription status.
- ❖ Switch decisions are **made by FDA** with the advice of advisory councils.
- ❖ Consumers can benefit from prescription-to-nonprescription switches because they **broaden access to important medications**. In addition, the nonprescription versions usually are **cost-effective for consumers and third-party insurers**.
- ❖ *A survey found that consumers save up to \$750 million a year as a result of using nonprescription cough and cold medications that once were available only by prescription. The same study demonstrated that physician visits for the common cold dropped by 110,000 a year between 1976 and 1989, suggesting that access to nonprescription products contributed to a reduction in office visits*

NONPRESCRIPTION MEDICATIONS- ECONOMICS VS REGULATIONS

- The nonprescription drug market represents about \$40 billion, or 60%, of the total pharmaceutical volume (units or number of packages) sold in the United States.
- **Five product categories** account for nearly 68% of sales in the nonprescription medications market: **respiratory, oral care, gastrointestinal, internal analgesics, and antiperspirants.**
- The estimated number of available U.S. Food and Drug Administration (FDA)-approved nonprescription drug products is well over 100,000, including more than 400 active ingredients that cover more than 700 therapeutic uses.

INTRODUCTION TO SELF-CARE

- Community pharmacists are the most accessible healthcare professional.
- No appointment is needed to consult a pharmacist and patients can receive free, unbiased advice almost anywhere.
- A community pharmacist is often the ***first health professional the patient seeks advice from*** and, as such, ***provides a filtering mechanism whereby minor self-limiting conditions*** can be appropriately treated with the correct medication and patients with more sinister pathology referred on to the GP for further investigating.

INTRODUCTION TO SELF-CARE -- CONTINUED

- Probably of greatest impact to community pharmacy practice globally is the increased prominence of self-care.
- Self-care is not new; people have always taken an active role in their own health.
- What is different now is the attitude towards self-care by policy makers, healthcare organisations, not-for-profit agencies and front-line healthcare workers.
- Health improvements have been seen in people adopting health-enhancing behaviours rather than just through medical intervention.

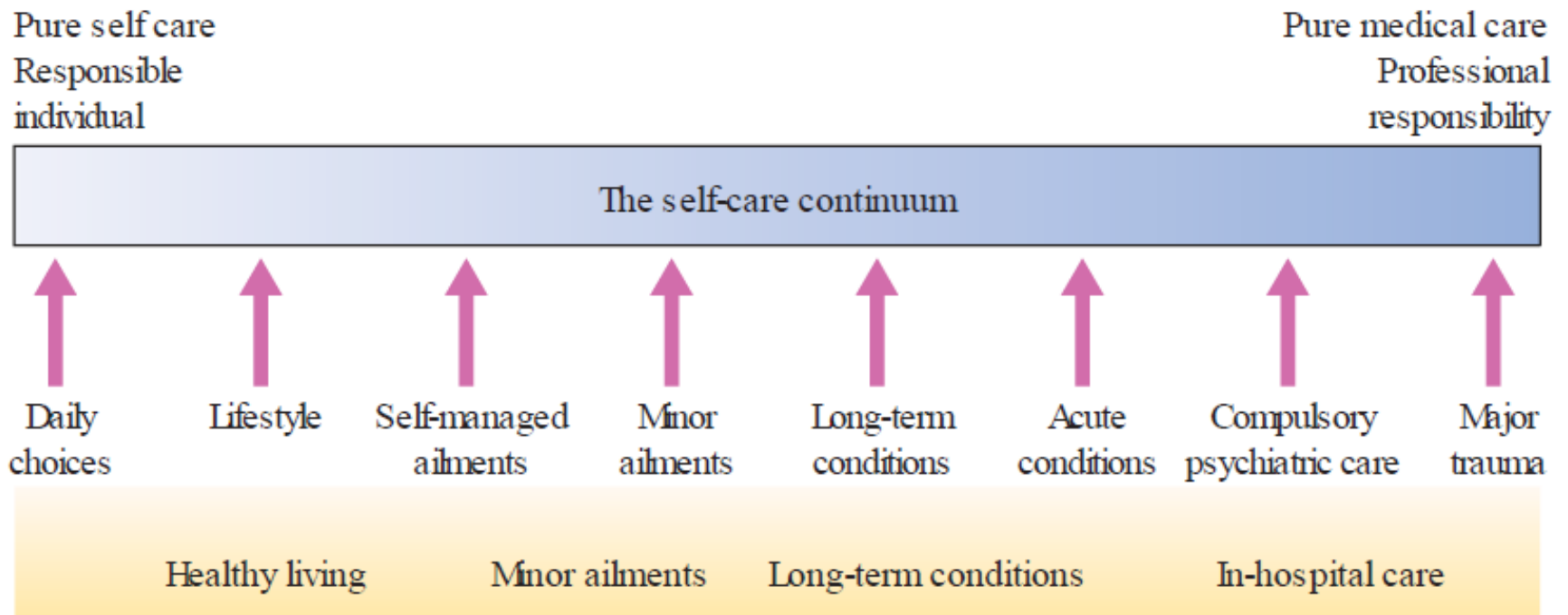
INTRODUCTION TO SELF-CARE – CONTINUED (2)

- In the UK the self-care **forum** (<http://www.selfcareforum.org/>), whose purpose is to **promote** self-care and embed it in everyday life, was established.
- Fundamentally, the concept of self-care puts responsibility on individuals for their own health and well-being.
- The World Health Organisation **defines** self-care as '*the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider*'.

INTRODUCTION TO SELF-CARE – CONTINUED (3)

- Self-care has been described as a continuum (Fig. 1), starting with individual choices on health (e.g., taking exercise), moving through to managing their own ill health (e.g., self-medicating) either on their own or with help.
- As people progress along the continuum, *more facilitation by others* is required until a person needs fully managed care.

FIGURE 1: THE SELF-CARE CONTINUUM



WHAT IS SELF-MEDICATION?

- ✓ Self-medication is just one element of self-care and can be defined as...
- ✓ *The selection and use of medicines by individuals to treat self-recognised illness or symptoms.*
- ✓ How these medicines are made available to the public **vary** from country to country, but all have been approved by **regulatory agencies** as safe and effective for people to select and use without the need for medical supervision or intervention.

WHAT IS SELF-MEDICATION? (CONTINUED)

- In many countries (e.g., Australia, New Zealand, France, Sweden, Canada, UK) regulatory frameworks support **reclassification** of medicines **away from** prescription-only control by having a **gradation in the level of medicine availability**, whereby certain medicines can only be purchased at a pharmacy. These **'Pharmacy medicines'** usually **have to be sold either by the pharmacist or under his or her supervision**.
- Over the last 30 years this approach to reclassification has seen a wide range of therapeutic agents made available to consumers, including **proton pump inhibitors** (US, EU-wide), **orlistat** (EU-wide), **triptans** (UK, Germany) and **beta-2-agonists** (Singapore, Australia).

Do you usually make an appointment to see your GP when you have any of the following illnesses?

- Athletes Foot
- Cold
- Constipation
- Cough
- Cystitis
- Diarrhoea
- Earache
- Fever
- Hay Fever/Allergic Rhinitis/Allergies
- Head lice
- Indigestion

- Insect Bites/Stings
- Minor Burns/Cuts
- Mouth Ulcers
- Sore Throat
- Sprains/Strains
- Teething
- Threadworm
- Vaginal Thrush
- Verruca
- Viral URTI
- Warts

If the answer is yes, then there is now a quicker and easier way for you to receive advice and treatment for these conditions, without having to see your GP. Instead you can see your pharmacist for a consultation.

Pharmacists in Camden can now give advice and treatment for any of the conditions from the above list. All you have to do is ask your GP receptionist at the GP Practice you are registered with to put you on the Minor Ailments scheme and give you a Patient Passport. You can use this passport each time you want to receive advice and treatment for your minor ailment.

This scheme is FREE and it means you do not have to wait for an appointment. If you do not normally have to pay for your prescriptions then any medicine the pharmacist gives you will be free. If you normally have to pay prescription charges many of the medicines maybe cheaper to buy from the pharmacist, who will advise you.



For more details on the scheme look out for Minor Ailments Patient Information Leaflets at your GP Practice and local pharmacy.

NHS
Camden
Clinical Commissioning Group

GENERAL DESCRIPTION OF BELIEFS IN DIFFERENT POPULATION GROUPS

SELF-MEDICATION APPLICATIONS??

1. Concepts of independence and interdependence

→ Autonomy vs helping the overall family structure

2. Acceptance of intergenerational households

→ several generations living together, different dynamics of social and family support for self-care may exist

3. Gender roles within the family structure

→ In intact family units, women may have a greater role in influencing self-care practices of the family.

GENERAL DESCRIPTION OF BELIEFS IN DIFFERENT POPULATION GROUPS (CONTINUED)

4. Family traditions related to **Complementary** and **alternative medicine (CAM)** use

→ Use indigenous or non-Western treatments as part of selfcare compared with whites

5. Role of friends

→ Friends, godparents, and “fictive kin” (very close friends in family-like relationships) can be relied on for support as much as family

6. **Religious** and spiritual beliefs of different cultures

→ The role of God and spiritual healing may influence how persons from a cultural group use and/or accept self-care practices.

TABLE 3–5 Examples of Cultural Behaviors Among Selected Populations^a

Group (heritage)	General Characteristics
Hispanic	• May actively involve family in health care • May use <i>curanderos</i> and <i>curanderas</i> (traditional healers) • May use home remedies, mostly teas or herbal remedies • May use religious medals for good luck • May believe that health is a matter of “luck” or “fate” • May have an attitude toward recovery that is pessimistic (“fatalism”) • May believe that illnesses are classified as hot and cold, with treatment chosen depending on the classification of the disease
Asian	• May stress the importance of family • May seek balance between forces to define health (<i>yin</i> and <i>yang</i>) • May believe that illnesses are caused by an imbalance of cold and hot forces • May use Eastern medicine, herbal products, Ayurvedic practices (India), or other CAM modalities • May not trust Western medicine

TABLE 3–5 Examples of Cultural Behaviors Among Selected Populations^a

Group (heritage)	General Characteristics
Black (not recent immigrant)	• May stress importance of biological and fictive family • May use home remedies and folk medicine
	• May distrust the health care system because of previous unfavorable experiences • May stress the importance of religion in achieving cure
American Indian	• May use sweat lodges as a means of cure • May use herbal medicine including natural roots • May use prayer for cure of illnesses • May believe that health is a harmony with “Mother Earth” • May use healers (medicine man or woman, shaman)
White	• May have non-nuclear family structures and non-traditional family roles as a result of cohabitation, divorce, and remarriage • May report more pain than people of other races • May have suboptimal health habits including overconsumption of food, often of poor nutritional quality • May have defined (formal) religious practices and a belief in one God and life after death

COMMUNICATION SKILLS

- The ability of the community pharmacist to diagnose the patient's presenting signs and symptoms is a significant **challenge**.
- Given that, unlike most other healthcare professionals, community pharmacists **do not normally have access to the patient's medical record** and thus **have no idea** about what the person's problem is until a conversation is initiated.

COMMUNICATION SKILLS - CONTINUED

- Having said this, a number of studies have shown that **patient history** taking is by far the most important element of arriving at a correct diagnosis.
- Although performing physical examinations and conducting laboratory investigations do improve the odds of getting the diagnosis right.

COMMUNICATION SKILLS – CONTINUED (2)

- It is vital, therefore, that pharmacists possess **excellent communication** skills to ensure the correct information is obtained from the patient.
- This will be drawn from a combination of:
- **Good questioning technique**
- **Listening actively to the patient**
- **Picking up on non-verbal cues.**

COMMUNICATION SKILLS – CONTINUED (3)

- Some community pharmacies have **JOB DESCRIPTIONS** and specific duties assigned to different technicians and clerks. **This helps to keep an efficient workflow, maximize patient care activities, and minimize medication errors.**
- This type of system frees up **the pharmacist to provide counseling and other value-added services to patients.**
- A technician run dispensing process.
- May serve as a role model to students on how to take phone calls from patients and triaging calls from other health care providers.

PATIENT COUNSELING

- Pharmacists are often the only health care providers focusing patient education on medication:
 - *how to take it?*
 - *what to expect?*
 - *and side effects and drug interactions.*
- Indian Health Service (IHS) Counseling Model is an effective strategy for patient counseling because it **utilizes open-ended questions and feedback (final verification) strategies**, which make communication between the pharmacist and patient more efficient and engaging.

PATIENT COUNSELING (CONTINUED)

- Pharmacists often **use print material** as a teaching aid or supplementary material during the educational process.
- It is important for students to understand that some patients are completely illiterate (13%-40%) or marginally illiterate (20%). **The average reading level for the general public is at the 7th-8th grade level.**
- Therefore, students should keep in mind the **readability** of print material as they develop it.

CLINICAL REASONING

- Whether we are conscious of it or not, most people will - at some level - use clinical reasoning to arrive at a differential diagnosis.
- Clinical reasoning relates to the ***decision-making processes associated with clinical practice.***
- It is a **thinking process** directed towards enabling the pharmacist to take appropriate action in a specific context.

CLINICAL REASONING - CONTINUED

- It fundamentally differs from using **acronyms** in that it is built around clinical knowledge and skills that are applied to the individual patient.
- **It involves recognition of cues and analysis of data.**
- Very early in a clinical encounter, and based on limited information, the person will arrive at a small number of **HYPOTHESES**.

CLINICAL REASONING – CONTINUED (2)

- The pharmacist then sets about **testing** these hypotheses by **asking** the patient a series of questions.
- The answer to each question allows the pharmacist to **narrow down the possible diagnosis** by either **eliminating** particular conditions or **confirming** his or her suspicions of a particular condition.
- Once the questioning is over, the pharmacist should be in a position to differentially diagnose the patient's condition.

CLINICAL REASONING – CONTINUED (3)

- In addition, clinical experience (pattern recognition) also plays a part in the process.

→ Depending on EPIDEMIOLOGY

- Therefore, much of daily practice will consist of seeing new cases that strongly resemble previous encounters and comparing new cases to old.

KEY STEPS IN THE PROCESS

- 1. Formulating a diagnosis based on the patient and the initial presenting complaint**
- 2. Asking questions**
- 3. Confirm facts**

PHYSICIAN CONSULTS

- Using appropriate communication strategies during physician consultations is important.
- Pharmacists should use the right words during a consult, to **be assertive, but not aggressive**, and to be ready to provide clinical recommendations.
- In other words, pharmacists' recommendations should be **concise, provide physicians with information that they may not know** (eg: patient adherence to their regimen or other medications that have been prescribed by other providers), **and suggest potential solution(s) to drug therapy problems that had been identified.**
- ***During conflict***, control one's anger, and try **not** to take the conflict that is occurring personally