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PITFALL OF OTC MEDICATIONS

Neha Chopra, Priyanka Keshri*, Aditi Sharma, Shakhi Ghosh, Gaurav Kishore Singh

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***Corresponding Author**
Priyanka Keshri
Assistant Professor, SOP,
ITM University, Gwalior.

INTRODUCTION

The term ‘patient' refers to a person who receives health care services, and its meaning has evolved outside of the context of commercial markets and without respect to the availability or source of payment for health care. Many active components that were previously solely available as prescription-only (Rx) medications have been available over-the-counter (OTC) in recent decades. Over- the-counter medicine is also known as OTC or nonprescription medicine.

Preparations acquired without a medical prescription at pharmacies, supermarkets, or drugstores, as well as pharmaceuticals from family medicine cabinets that had not been previously prescribed, were classified as ‘self-medication.' Self-prescription (the use of prescription medicines without a physician prescription, whether the availability of medications is due to leftover medications from previous prescriptions or to illegally acquired medicines) constitutes a clear non- responsible self-care behavior, since ‘prescription only’ status indicates that a particular medication cannot be safely used without a physician’s diagnosis and surveillance.

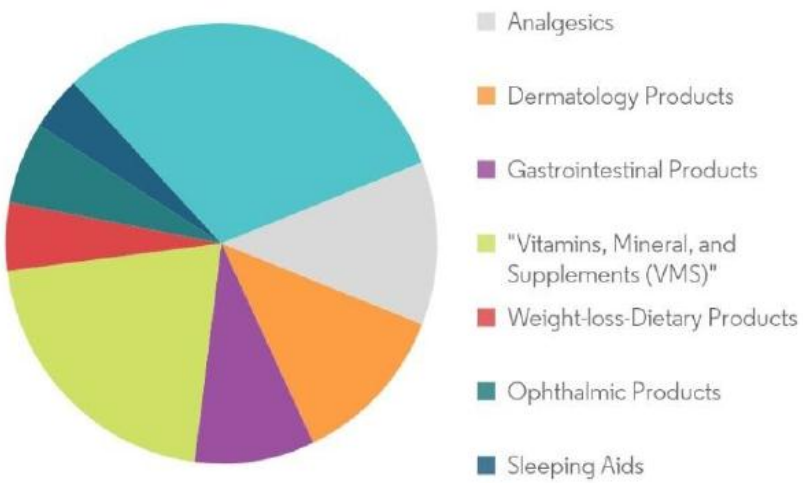
Advantages: Undoubtedly, self-medication does have some advantages, such as getting patients more involved in their treatment, which leads to an increase in the proper use of medications, which can result in overdosing or duplication of therapy. When compared to prescription drugs, using OTC drugs has a number of benefits, including fewer doctor visits and reduced prices. Misuse of OTC medications, on the other hand, can lead to unpleasant reactions, drug interactions, overdose, and other medication-related problems. As a result, the general public should be educated on how to safely use OTC medications in order to enhance their awareness of potential risks and promote responsible self-care.

Disadvantages: Inappropriate self- medication such as the risk of adverse drug reactions, risk

of wrong use of drugs, risk of missing the diagnosis, risk of drug dependence, risk of drug-drug, drug-food, drug-disease interactions, risk of overuse or toxicity.

Analgesics, laxatives, antithrombotic agents, antacids, cough and cold preparations, antihistamines, dermatologicals, throat preparations, nose preparations, and anti-diarrheals are the ten categories of Anatomical Therapeutic Chemicals (ATC). When taken properly, these medications are usually safe, but when used for long periods of time or at high doses, the risk of side effects increases. The most commonly utilized pharmaceuticals are the OTC non-steroidal anti-inflammatory drugs (NSAIDs) ibuprofen, naproxen, and aspirin, as well as the analgesic acetaminophen. They are used by approximately 23% of the population around the world, particularly for the hepatic, gastrointestinal, cardiovascular and renal systems.

Survey of OTC Drug



The global data revealed that the most commonly used medicines were analgesics (87.9%), antipyretics (64.8%), and antibiotics (34.5%).

Adverse drug reactions, incorrect drug use, missed diagnoses, drug dependence, drug-drug, drug-food, drug-disease interactions, overuse or toxicity are all risks associated with inappropriate self-medication.

Antibiotics, mild analgesics, and several anti-inflammatory medications are all accessible over-the-counter.

Concerns with medication safety have risen due to older adults' use of OTC medications

containing diphenhydramine or doxylamine (DIPH/DOX),that increase the risk of hepatic and renal insufficiency, drug interactions, adverse events, and unintended anticholinergic effects in the elderly patient. OTC medications can be classified according to the World Health Organization.

- **Pain** is the most common complaint among patients seeking care in an emergency department (ED), yet there are few studies describing the use of over-the-counter pain medications in an ED population. These medications are safe when used as directed, but the incidence of adverse effects increases when the recommended doses of these medications are exceeded. NSAID (47 %) were the most frequently used pain medications.
- **NSAIDs**

The Non-steroidal anti-inflammatory drugs (NSAIDs) have been used to treat a variety of ailments, including the common cold, heartburn, headaches, and musculoskeletal discomfort. Despite their favorable safety record, NSAIDs can nevertheless cause serious side effects.

NSAIDs are known to cause gastrointestinal side effects ranging from dyspepsia to life-threatening events such GI hemorrhage (2–10). Approximately 3% of prescription NSAID users encounter the most serious adverse effects—peptic ulcer, perforation, or bleeding—every year, and 25– 30% experience GI side effects, which frequently necessitate additional medical attention.

Patients will continue to utilize these treatments as long as they are availableover the counter. Clinicians should be on the lookout for signs of NSAIDs having an effect on the gastrointestinal tract.

The need for non-opioid analgesic availability limits is reasonable, yet it isdebatable.

NSAID use accounts for a larger burden of ADEs (15.4%) than anticoagulants (10.2%), one of the Department of Health and Human Services' top priority drugs in its National Action Plan for ADE prevention.3,4 Unintentional overdoses of acetaminophen result in 14,000 emergency department visits, and up to 50% of all acute liver failures per year.

- **PPA** [phenylpropanolamine] is widely used as over-the-counter cold remedies and anorectic agents easily purchasable at the pharmacies all over the world. Despite its long-

standing availability, the adverse reactions continue to be documented, even when it is taken as recommended dosage. PPA is less known to cause myocardial damage, as only 8 cases have been reported so far, all in younger females. Many are available in both prescription and over-the counter (OTC) dosages.

Overstimulation with catechol-amines or a catecholamine oxidation product has also been linked to a direct cardiac toxic reaction and a reduction in myocyte survival. These findings indicate that the mechanisms of PPA- induced myocardial damage may involve coronary vasoconstriction which may lead to Myocardial infarction.

The use and advertising of drugs and Greater access to medications and health information and greater participation in medical decision making have dramatically changed the public's attitude regarding control over health and life quality. As a consequence, traditional paternalistic, physician-centered model of patient/health care provider relationship and health care professionals' authority have been undermined, and new participative models of health professional/patient relationship have reporting data for safety signal detection of OTC medicines**.**

To treat self-recognized illnesses or symptoms without consultation of health rg) care professionals".

Inappropriate self- medication such as the risk of adverse drug reactions, risk of wrong use of drugs, risk of missing the diagnosis, risk of drug dependence, risk of drug-drug, drug-food, drug-disease interactions, risk of overuse or toxicity.

Many types of antibiotics, mild-analgesics, and many of the anti-inflammatory drugs are all available OTC.

Older people are particularly vulnerable to ADE risk due to aging factors currently; there is a risk of overuse of OTC drugs, especially analgesics, in the whole population, and especially among the elderly.

Evidence further suggests that more than half of older adults (geriatric population) who take OTC medications are not using those medications safely. In fact, OTC related adverse drug events (ADEs) involving older adults are estimated to result in almost 100,000 hospitalizations nationally each year. Additional ADEs, especially with older adults, can

include increased rates of falls, insomnia, delirium, cognitive impairment, and severe gastro hepatic problems**.**

While much attention has been placed on in-hospital **pediatric medication** errors and associated morbidity and mortality, less is known about the public health impact of out-of-hospital medication errors, especially those involving over-the- counter (OTC) medications. because preclinical developmental toxicity studies are typically required and performed only in non-human animal species and may not be entirely predictive of the risk or safety of use of the same product at clinically relevant doses in humans.

Others

- Cannabidiol (CBD) can be bought as an over-the counter (OTC) food supplement in a variety of forms, such as capsules, oils, cigarettes or an e- liquid.

Neuroimaging studies have shown that it has effects on brain activity and can modulate both the endo-cannabinoid and other neurotransmitter function in both volunteers and patient.

- **Pregnancy**

The same concerns apply to over-the-counter (OTC) medications and products. Despite the common misperception that an OTC designation indicates that the product is known to be safe for use in pregnancy, limited pregnancy safety data exist for the majority of these products as well.

However, there are still several challenges in conducting research focused on determining which medications are safe during pregnancy, including OTC products. Different outcomes and any given product may be taken only sporadically; and longer-term outcomes such as cognitive and behavioralperformance in prenatally exposed children are difficult and costly to ascertain. An additional major methodological challenge in studying the safety of OTC medications taken in pregnancy is the fact that, unlike prescription medications, there may be no record that the drug was dispensed or taken.

- **STDs**

Of these, approximately 14% take OTC medications several times a week and another 15% take OTC pain medications daily. Human immunodeficiency virus (HIV)-infected individuals commonly have multiple health related problems due todisease progression, complications of

opportunistic infections, and adverse effects of prescription medications. These health problems may prompt HIV-infected persons to seek traditional or alternative medical care or engage in other self-care practices.2,3 Between 41% and 100% of HIV-infected patients use OTC medications for self-care, 2,4-6 ranging from one to as many as 11 different products concurrently.

They should not be used by anyone with heart disease, high blood pressure, thyroid disease, diabetes, or an enlarged prostate. They are meant to treat patients with mild, intermittent asthma. However, by some estimates, 20% of the people who use them actually have mild-to-moderate persistent asthma and should be using prescription controller drugs. All too often, the following dangerous scenario plays out: because the individual typically is not being seen by a doctor, he or she is not getting the long-term anti-inflammatory drugs that are needed. As a result, he orshe relies too heavily on the inhaled OTC quick relief asthma inhaler.

Heart

PPA [phenylpropanolamine] is widely used as over-the-counter cold remedies and anorectic agents easily purchasable at the pharmacies all over the world. Despite its long-standing availability, the adverse reactions continue to be documented, even when it is taken as recommended dosage. PPA is less known to cause myocardial damage, as only 8 cases have been reported so far, all in younger females.

Many are available in both prescription and over-the counter (OTC) dosages.

GI

NSAIDs are well recognized to cause adverse GI reactions, ranging from dyspepsia to life threatening complications, such as GI bleeding (2–10). About 3% of prescription NSAID users annually experience the most serious side effects— peptic ulcer, perforation, or bleeding—and 25–30% experience GI side effects, often leading to additional medical care. OTC NSAIDs, including aspirin, comprise a considerable proportion of total OTC drug use in the United States and are often used on a chronic basis.

However, even low-dose OTC NSAIDs increase risk of GI bleeding and perforation**.** Associations between unhealthy lifestyle and CH emphasize the need for lifestyle interventions concurrent with medical management of medicationoveruse headache.

These facts, compounded by the wide availability of these medications, raise the level of concern for all physicians who interact with children and adolescents.

While these drugs remain accessible over the counter, patients will continue to use them. Clinicians should therefore be vigilant for evidence of NSAID impact on the gastrointestinal tract.

The need for restrictions on non-opioid analgesic availability seems sensible but remains disputed**.**

The majority of healthcare is not delivered by healthcare services but is, in fact, self-managed, as evidenced by over-the-counter (OTC) medicine sales. In 2010, more than £2.3 billion was spent by the general public on OTC medicines, which equates to 973 million packs (Proprietary Association of Great Britain, 2011). Despite these figures, many people still end up in GP surgeries wanting treatment and advice for conditions that are acute and self-limiting, and this accounts for a substantial.

To tackle this problem at a local level, most GP surgeries run minor illness clinics staffed by nurses; however, at policy level the UK government has embraced the self-care concept (Department of Health (DH), 2003; DH, 2005; DH, 2006; DH, 2007). This has led to the creation of NHS walk-in centers, telephone helplines (e.g. NHS Direct/24) and greater access to medicines without the need for aprescription.

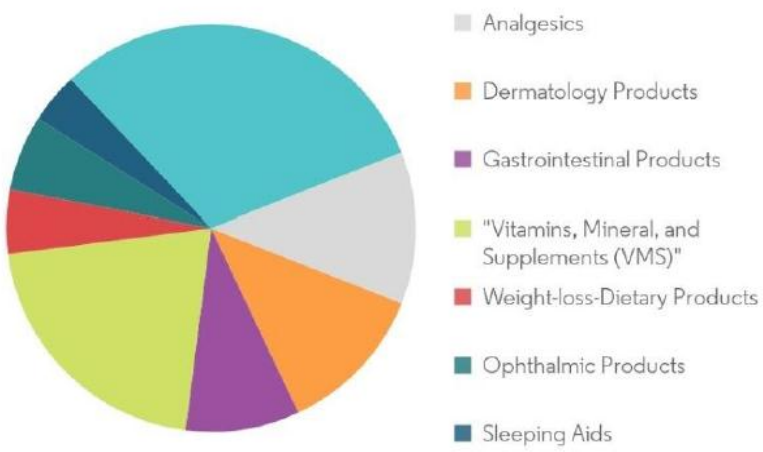


Figure 1: Global OTC Drugs Consumption.

- Analgesics
- Dermatology Products

- Gastrointestinal Products
- Vitamins, Mineral, and Supplements (VMS)
- Weight Loss/Dietary Products
- Ophthalmic Products
- Sleeping Aids
- Others - Cannabidiol (CBD) is available in a variety of forms as an over-the- counter (OTC) nutritional supplement, including capsules, oils, smokes, and e- liquid. In both volunteers and patients, neuroimaging studies have demonstrated that it has an influence on brain activity and can modify both endo-cannabinoid and other neurotransmitter function.

Although there is enormous consumer interest in CBD, there is little evidence that OTC CBD products have health benefits, and their safety has not been investigated.

The unintentional misuse of over the-counter sleep aids among older adults is an important public health problem and a focus of Healthy People 2020.

Over-the-counter (OTC) analgesics are among the most widely prescribed and purchased drugs around the world.

Overdoses of OTC analgesic drugs can induce acute liver failure (ALF) either directly or indirectly after their biotransformation.

Although there were no deaths from pediatric medication involving CCMs, 70% of OTC CCM medication errors involving a significant AE led to HCF evaluation and almost 25% required admission.

Phenylpropanolamine (PPA) is widely used as over-the-counter cold remedies and anorectic agents easily purchasable at the pharmacies all over the world. Despite its long-standing availability, the adverse reactions continue to be documented even when it is taken as recommended dosage. It is well known that PPA is a sympathomimetic amine and produces diffuse vaso-constriction. Overstimulation with catechol-amines or an oxidative product of catechol-amines also have been known to yield direct cardiac toxic reaction and decreased myocyte viability. These findings indicate that the mechanisms of PPA-induced myocardial damage may involve coronary vasoconstriction which may lead to Myocardial infarction**.**

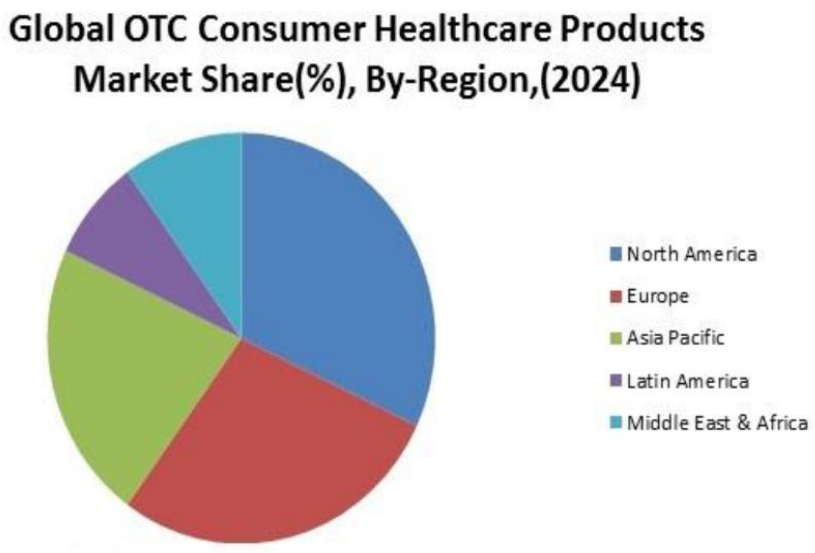


Figure 2: Global OTC Consumer market share (by Geography).

- North America
- Europe
- Asia Pacific
- Middle East & Africa
- Rest of the World

The following nations had OCs available without a prescription but only after being screened for eligibility by trained pharmacy employees, 56 countries had OCs available informally without a prescription, and 45 countries required a prescription. Given the continually high rate of unplanned births worldwide—44%, according to some estimates—making OCs available over-the-counter in more settings has the potential to lower obstacles to access, increasing use of this efficacy.

USA

An American survey revealed that up to 41% of consumers believe that non- prescription medications are too weak to cause any problems.

According to previous studies, OTC drugs are reported spontaneously to some level; nevertheless, the extent of ADR reporting for OTC medicines appears to be highly variable.

OTC NSAIDs, such as aspirin, account for a significant fraction of total OTC drug consumption in the United States and are frequently used on a long-term basis.

Reports for non-analgesic OTC medicines comprised only 4% of all ADR reports, and a study examining ADRs associated with self-medication using data from the French regional Midi-Pyrenees pharmacovigilance dataset reported ADRs from self-medication made up only 1.3 percent of all ADR complaints.

A study reported that 12% of older adults (C65 years old) in the United States use OTC sleep medications. Almost half (44%) of older adults in the United States experience disturbed sleep at least a few nights each week and frequently use OTC sleep medications.

According to a 2008 study, 10% of American youngsters were given a CCM (cough and cold medicine) per week. Thus, it is not surprising that OTC medications are frequently involved in out-of-hospital medication errors, including approximately a quarter of all out-of-hospital medication errors reported to (National poison data system) NPDS. Medication mistakes result in high healthcare utilization and have a major financial impact on the healthcare system. CCMs have been implicated in up to 7% of all medication overdose-related pediatric (Emergency departments) ED visits.

Europe

In Europe, it is estimated that around 10% of all medicine sales are for OTC medicines. According to the Ageing Population Report 2019, Europe's population aged 65 and up was 140,410 in 2019 and is anticipated to rise to 199,895 by 2050. Chronic condition prevalence rates are predicted to climb as the world's populationcontinues to age. However, as the senior population continues to expand, various old age disorders emerge, for which patients avoid visiting to hospitals in favour ofreceiving prescriptions and treatment at home. As a result of these causes, basic analgesic OTC products are becoming increasingly important and popular in the market.

In addition, rising healthcare expenditures necessitate greater accessibility and affordability of healthcare services. Self-medication with non-prescription medications is critical in this regard, as it enhances accessibility while also saving money. In Europe, self-medication is also on the rise. According to the Associationof the European Self-medication Industry, non-prescription medicinal products account for one out of every two packets of medications supplied in Europe. The widespread usage of over-the-counter drugs has been related to significant cost savings for healthcare providers in a variety of nations. OTC drugs allow customers to take care of themselves when seeing a physician or doctor isn't necessary, which

is projected to fuel market growth.

Over the last 15 years, the **UK's** health policy has emphasised patient empowerment and encouraging people to practise self-care. This has been aided by the deregulation of drugs from prescription-only to non-prescription status, which has increased the number of medicines available for consumer purchase and enabled for self-management of a greater variety of illnesses.

Asia pacific

Product developments, high penetration in rising nations like India and China, and pharmaceutical firms' preference for OTC pharmaceuticals over prescription drugs are driving growth in the Asia-Pacific over-the-counter (OTC) drugs market. This can be linked to the fast rising population as well as a rise in the population's disposable income, which may create a critical mass of people who can acquire OTC medications.

Supermarkets are contributing to the expansion of the OTC drug industry in Asia- Pacific, along with new channels of accessibility in emerging markets through retail stores. However, the market's expansion is projected to be hampered by a lack of public knowledge and inaccurate self-diagnosis.

Middle East and Africa

These four medications are also available in multi-ingredient formulations, accounting for 45 percent of acetaminophen and 26% of aspirin use, raising the risk of hazardous overdosing.

The global over the counter (OTC) drugs market is likely to record the highest growth rate in the emerging markets of Latin America and Southeast Asia over the coming years. This can be attributed to the rapidly growing population, coupled with the growing middle class in these regions and increase in disposable income of the population, which will add critical mass to the population available to access OTC medication. Along with new channels of the accessibility in emerging markets in retail outlets, supermarkets are also contributing to the growth of the OTC medication market in the emerging economies.

CONCLUSION

People are generally hesitant to acknowledge that they are dependent on a medicine. But the major issue isn't that they don't want to disclose their addiction to others; it's that they don't want to admit it to themselves in the first place. They tend to blame everything on financial

difficulties or troubled relationships, ignoring the true culprit: OTC drug misuse. If left untreated, addiction grows stronger and stronger, causing major health problems and utterly destroying the abuser's life.

OTC medications, while typically harmless, can be extremely addicting if used incorrectly. If you or a loved one thinks they may have acquired an addiction to a prescription, don't waste any time and get expert assistance right away. Pharmaceutical counseling provided by community pharmacies is particularly crucial when medications are purchased over the-counter (OTC), without advice given by a physician.

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