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## **Frequently used Over-the-counter (OTC) Medicines in Underlying Risks: A Comprehensive Review**

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### **Abstract**

**Problems:**Chronic used of over-the-counter (OTC) medicines may initiate permanent damage and chronic diseases.

**Experimental approach:**Comprehensive review.

**Findings:**Over-the-counter (OTC) medicines are used generally for treating minor illnesses. It is mainly used for the common acne, facial pain, congestion, runny nose, fever, headache, hoarseness, itchy eyes, sneezing, sore throat cough and cold, pain, diarrhea and stomach discomfort, ulceration among others. More availability and less costly of over the counter drugs (OTC) initiate several chronic diseases. In short-term effects impaired judgment, nausea, loss of coordination, headache, vomiting, loss of consciousness, numbness of fingers and toes, abdominal pain, irregular heartbeat, aches, seizures, panic attacks, psychosis, euphoria, cold flashes, dizziness, and diarrhea and in long-term effects addiction, restlessness, insomnia, high-blood pressure, coma and so on, or even death.

**Conclusion:**If we do not consider proper use of OTC drugs it may initiate several causes of

diseases. Irrelevant uses of OTC drugs promote permanent chronic diseases. So OTC drugs should be controlled and properly used.

**Key Words:**OTC drugs, Uses, Abuses, Pregnancy, Bangladesh.

## **Introduction**

Self-care is becoming enhanced popular among health care consumers. The over-the-counter medications are available for consumers to treat numerous ailments without the supervision of a health care professional. Many medications are available without a prescription was previously classified as prescription-only products. Enhancing patient involvement in the diagnosis and treatment of common ailments has led to a greater interest in self-care and an increase in the use of nonprescription drug products. Nonprescription medications are accounted for about 60 percent of all medications used in the United States and may be used to treat or cure about 400 ailments. Thirty percent of new over-the-counter (OTC) drugs marketed between 1975 and 1994 were products that had been changed from prescription to OTC status. This article reviews the process by which drug products are approved for OTC use and changed from prescription to OTC status, lists the criteria are matched before such a change may be approved, describes the potential impact of reclassified products on the U.S. health care system, discusses patient counseling about OTC products, and outlines the relevant drug category, active ingredients, indications for and usual dosages of products that have recently modified from prescription to OTC status<sup>[1]</sup>. Although most Canadians believe that OTC medicines are safe and effective, they can pose some risk through side effects and interactions if people do not take them with due care. With notable exceptions, people in Canada can purchase OTC medicines from pharmacies or non-pharmacy outlets such as convenience stores. Global trends in medicine-related legislation are leading to more of these products ending up in retail outlets other than pharmacies<sup>[2]</sup>. Example of some OTC drugs are Antiperspirants (not deodorants), Tooth pastes (not whitening only), Acne remedies, Antiplaque, Hair regrowth aids, Contraceptive, Hospital use topical microbial, Sunscreen<sup>[3]</sup>. The intentional abuse of prescription (Rx) and over-the-counter (OTC) medications to get high is now available among today's teen population, according to a national study released by the Partnership for a Drug-Free America®. The Partnership's 18th annual study of teen drug use and attitudes confirms that teenagers abused Rx and OTC medications than a variety of illegal drugs like Ecstasy, cocaine, crack and meth. Nearly one in five teens (19 percent or 4.5 million) report abused prescription medications to get high and one in 10 (10 percent or 2.4 million) report abusing cough medicine to get high. "This study removes any doubt that intentional abuse of medications among teens is a real issue threatening the health and well being of American families," said Steve Pasierb, president & CEO of the Partnership. "We have a situation where a widespread and dangerous teen behavior has become normalized and has found its way into our homes. These findings should serve as a wake-up call to parents that their teen is facing a drug landscape that did not exist when they were teens. The abuse of prescription and over-the-counter drugs has taken root among America's teens and the behavior is not registering with parents. Unless we all take action, it is a problem that will only get worse. Released today in Washington, D.C., the 2005 Partnership Attitude Tracking Study (PATS)

surveyed more than 7,300 teenagers in grades 7-12 (margin of error: +/-1.5 percent). Top-line findings from this nationally projectable tracking study indicate the culture of "pharming" .

Abusing a host of medicines and chemical products intentionally to get high and established itself among America's teen population: Nearly one in five (19 percent or 4.5 million) teens has tried prescription medication (pain relievers such as Vicodin and OxyContin; stimulants like Ritalin and Adderall) to get high. One in 10 (10 percent or 2.4 million) teens report abusing cough medicine to get high; and Abuse of Rx and OTC medications is on par or higher than the abuse of illegal drugs such as Ecstasy (8 percent), cocaine/crack (10 percent),methamphetamine (8 percent) and heroin (5 percent). Two in five teens (40 percent or 9.4 million) agree that Rx medicines, even those are not prescribed by a doctor, are "much safer" to use than illegal drugs. Nearly one-third of teens (31 percent or 7.3 million) believe there's "nothing wrong" with using Rx medicines without a prescription "once in a while;" Nearly three out of 10 teens (29 percent or 6.8 million) believe prescription pain relievers even if not prescribed by a doctor are not addictive. More than half of teens (55 percent or 13 million) don't strongly agree that using cough medicines to get high is risky <sup>[4]</sup>.

### **Characteristics of the OTC Drugs <sup>[3]</sup>**

1. Acceptable safety margin
2. Low misuse and abuse potential
3. Consumer self recognize, self diagnose and self treat.
4. Can be adequately labeled
5. Health Practitioner not needed for safe and effective use of the product

### **Broad Therapeutic Classes of OTC Medications <sup>[5]</sup>**

1. Analgesics and antipyretics
2. Cold, cough, and allergy products
3. Nighttime sleep-aids
4. Gastrointestinal products
5. Dermatological products
6. Other topical products (including dermal and vaginal antifungals, anorectal medications, head lice products, hair loss products, and otics )
7. Ophthalmic products
8. Oral health care products
9. Menstrual products
10. Nicotine replacement products
11. Weight loss aids
12. Vaginal contraceptives and emergency contraceptives.

**Uses of OTC drugs**

<b>Symptom</b>	<b>How to Treat</b>	<b>Generic Ingredients</b>
Generalized aches/pains	Analgesic drug	aspirin, acetaminophen, ibuprofen, naproxyn <sup>[6]</sup>
Facial pain	Analgesic drug	aspirin, acetaminophen, ibuprofen, naproxyn <sup>[6]</sup>
Stuffy nose/ congestion	Decongestant drug	pseudoephedrine, phenylephrine, oxymetazoline, naphazoline <sup>[6]</sup>
Productive cough	Expectorant	Guaifenesin <sup>[6]</sup>
Nonproductive cough	Antitussive drug	Dextromethorphan <sup>[6]</sup>
Runny nose	Antihistamine drug	brompheniramine, diphenhydramine, chlorpheniramine, clemastine, loratadine, pheniramine <sup>[6]</sup>
Fever	Antipyretic drug	aspirin, acetaminophen, ibuprofen, naproxyn <sup>[6]</sup>
Headache	Analgesic drug	aspirin, acetaminophen, ibuprofen, naproxyn <sup>[6]</sup>
Hoarseness	Analgesic drug - Expectorant	aspirin, acetaminophen, ibuprofen, naproxyn, guaifenesin <sup>[6]</sup>
Itchy nose/eyes/throat	Antihistamine drug	diphenhydramine, chlorpheniramine, clemastine, brompheniramine, pheniramine <sup>[6]</sup>
Sneezing	Antihistamine drug	diphenhydramine, chlorpheniramine, clemastine, brompheniramine, pheniramine <sup>[6]</sup>
Sore throat	Anesthetic-Analgesic drug	benzocaine, benzyl alcohol, aspirin, acetaminophen, ibuprofen, naproxyn <sup>[6]</sup>

### **Over-the-Counter Medications in Pregnancy**

Pregnant women generally use over-the-counter medications. Although most over-the-counter drugs have an excellent safety profile, some have unproven safety and adversely affect the fetus. The safety profile of some medications may change regarding to the gestational age of the fetus. Because an estimated 10 percent or more of birth defects result from maternal drug exposure, the U.S. Food and Drug Administration has assigned a risk category to each drug. Several drugs have not been evaluated in controlled trials and probably will not be because of ethical considerations. The commonly used over-the-counter medications, acetaminophen, chlorpheniramine, kaolin and pectin preparations, and most antacids have a good safety record. Other drugs, such as histamine H<sub>2</sub>-receptor blockers, pseudoephedrine, and atropine/diphenoxylate should be used with caution. If use of smoking cessation products is desired, the intermediate-release preparations minimize the amount of nicotine while maintaining efficacy. With all over-the-counter medications used during pregnancy, the benefit of the drug should outweigh the risk to the fetus<sup>[6]</sup>.

### **Effective and Safe Use of OTC Medications**

1. Read product labels carefully. The labels contain essential information about the name, ingredients, indications for use, usual dosage, when to stop using the medication or when to see a doctor, possible side effects, and expiration dates.
2. Use a magnifying glass, if necessary, to read the fine print. If you do not understand the information on labels, ask a physician, pharmacist, or nurse.
3. Do not take OTC medications longer or in higher doses than recommended.
4. Note that all OTC medications are not safe for everyone. Many OTC medications warn against use with certain illnesses(eg, hypertension, thyroid disorders). Consult a health care provider before taking the product if you have one of the contraindicated conditions.
5. If taking any prescription medications, consult a health care provider before taking any nonprescription drugs to avoid unwanted drug interactions and adverse effects. Some specific precautions include the bellows:
6. Avoid alcohol if taking antihistamines, cough or cold remedies containing dextromethorphan, or sleeping pills. Because all these drugs cause drowsiness, combining any of them with alcohol may result in excessive, potentially dangerous, sedation.
7. Avoid OTC sleeping aids if you are taking a prescription sedative-type drug (eg, for nervousness or depression). Ask a health care provider before taking products containing aspirin if you are taking an anticoagulant (eg, Coumadin).
8. Ask a health care provider before taking other products containing aspirin if you are already taking a regular dose of aspirin to prevent blood clots, heart attack, or stroke.
9. Do not take a laxative if you have stomach pain, nausea, or vomiting, to avoid worsening the problem.
10. Do not take a nasal decongestant, a multisymptom cold remedy containing pseudoephedrine (eg, Actifed, Sinutab), an antihistamine-decongestant combination (eg, Claritin D), or the herbal medicines that may contain ephedra if you are taking a prescription medication for high blood pressure. Such products can increased blood

pressure and decrease or cancel the blood pressure–lowering effect of the prescription drug. This could lead to severe hypertension and stroke.

11. Store OTC drugs in a cool, dry place, in their original containers; check expiration dates periodically and discard those that have expired. If pregnant, consult your obstetrician before taking any OTC medications.
12. If breast-feeding, consult your pediatrician or family doctor before taking any OTC medications.
13. For children, follow any age limits on the label. Measure liquid OTC medications with the measuring device that comes with the product (some have a dropper or plastic cup calibrated in milliliters, teaspoons, or tablespoons). If such a device is not available, use a measuring spoon. It is not safe to use household teaspoons or tablespoons because they are different sizes and deliver varying amounts of medication. Accurate measurement of doses is especially important for young children because most of their medications are given in liquid form.
14. Do not assume continued safety of an OTC medication you have taken for years. Older people are more likely to have adverse drug reactions and interactions because of changes in heart, kidneys, and other organs that occur with aging and various disease processes.
15. Note tamper-resistant features and do not buy products with damaged packages <sup>[7]</sup>.

### **Understanding the Risks of OTC medications:**

Over-the-counter (OTC) medications may seem risk-free – after all, you don't need a doctor's prescription to buy them. Just because they are readily available doesn't mean you don't need to follow an OTC drug's directions carefully. Some OTC medicines show risks for people with certain medical conditions, as well as for pregnant women. Some drugs can interact adversely with other medications, food, or drinks. And if you take too much medication, use it for too long a period of time, or otherwise misuse the medication, you face other risks. Here's what you need to know about the most common types of OTC medicines <sup>[8]</sup>.

### **Pain relievers**

OTC pain relievers are typically used for mild pain or fever. The active ingredients in these medications are either acetaminophen or 1 of the nonsteroidal anti-inflammatory drugs (NSAIDs) – aspirin, ibuprofen, or naproxen sodium. These drugs are generally safe and free of side effects when taken as directed, but you need to be aware of several risks. First risk is liver damage from taking too much acetaminophen. Ibuprofen and naproxen can cause kidney damage or stomach bleeding in certain situations. Children and teens should not take aspirin for fever or flu because it increases the risk for an illness called Reye syndrome <sup>[8]</sup>.

### **Laxatives**

Laxatives show some risks if used improperly, but the most common problems that stem from laxatives are because of overuse. Typically, OTC laxatives are not recommended for people with mild constipation. For chronic constipation, your doctor may recommend 1 for a short period of time. If you use a laxative frequently, you may become reliant on laxatives to have a bowel movement. You may also need to take an increasing dose of a laxative to achieve the same effect <sup>[8]</sup>.  
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### **Heartburn remedies**

Traditional OTC drugs for heartburn are antacids with familiar household names, such as Roloids, Tums, and Maalox; they work by neutralizing acid in the stomach. Newer remedies, such as H2 blockers and proton pump inhibitors, literally halt the production of acid in the first place. Traditional antacids are typically made up of some combination of salts, which may cause diarrhea or constipation in some people. They may also interfere with absorption of some prescription medications. The H2 blockers and proton pump inhibitor drugs are generally free of these side effects, but they don't work for everyone, and they can interact with some prescription medications<sup>[8]</sup>.

### **Sleep aids**

OTC sleep aids don't cause "sleepwalking," as some prescription sleep medicines do, but they still have some risks. Some OTC sleep aids longer efficacy than 8 hours, which means you may still be drowsy after using the drug to sleep through the night. Another warning about OTC sleep aids, you shouldn't use them for longer than 2 weeks. A guideline that many people ignore to used. Most experts agree that if you still have sleeping problems after 2 weeks, you should see your doctor<sup>[8]</sup>.

### **Cough, cold, and allergy remedies**

Common OTC options include decongestants, antihistamines, cough suppressants, and expectorants. Make sure to select a drug that closely matches your symptoms and use it as directed. Some of these drugs do show risks for certain people. For example, if you have high blood pressure or heart disease, talk with your doctor before using OTC decongestants. Some older antihistamine medications, commonly called "first generation" antihistamines, cause drowsiness, as well as eye and mouth dryness, abdominal pain, and headaches. These side effects are much less common with some of the newer, "second generation" antihistamines, which often are labeled "nondrowsy" on their package. The FDA and the American Academy of Pediatrics advise parents not to give OTC cold and cough medication to infants or small children younger than 4 years old because of life-threatening side effects<sup>[8]</sup>.

### **Abuses of Over-the-counter (OTC) drugs**

In real sense, there is no 'prescription only drug' in Bangladesh at present. One can get any drugs from anywhere. Only need is money; no prescription indeed. Over the counter (OTC) drugs have emerged recently as drugs of serious misuse across Bangladesh, and other neighboring countries (Cheraghli et al,2009)<sup>[9]</sup>. Over-the-counter (OTC) drugs e.g. certain cough mixtures, cold medicines, analgesics, sleep aids, and antihistamines are abused for psychoactive effects, because they contain ingredients such as codeine, dextromethorphan, and diphenhydramine. In UK and Ireland, codeine is widely available in combination with paracetamol, aspirin, or ibuprofen as analgesic tablets, these tablets can be used recreationally to obtain the euphoric effects associated with opioids. Dextromethorphan was introduced as an antitussive in 1958, in response to the rampant recreational use of an addiction to codeine-based cough medicines at the

time. The perceived advantages of dextromethorphan in comparison to codeine were the lack of physical addiction, no abuse potential and the absence of a sedative-like effect from a normal dosage. However, when dextromethorphan is consumed in large quantities, it can cause effects similar to those of ketamine and phencyclidine (Romanelli and Smith, 2009). Diphenhydramine is an antihistamine, used therapeutically to manage urticaria, and in conjunction with opioids to potentiate analgesia. Diphenhydramine works via histamine H1 receptor blockade, therefore it has powerful hypnotic effects, and often used as a non-prescription sleep aid or a mild anxiolytic. The anticholinergic action of diphenhydramine can produce characteristic euphoria effects (Feldman and Behar, 1986). Concerning OTC drugs, findings on the trends in prevalence from 2002 through to 2004 indicated that dextromethorphan or paracetamol/codeine preparations have the highest lifetime prevalence of abuse in persons aged 12 years or older (Colliver et al., 2006). Prescription and OTC drugs comprise eight of the top 14 categories of drugs abused by 12th grade (i.e. the sixth class or final year secondary school) students (Johnston et al., 2010). Among young persons aged 12-17 years, 3.1% abused prescription drugs in a past month (SAMHSA, 2010b) <sup>[8]</sup>. Furthermore, 50% of teenagers have used prescription drugs either alone or in combination with other illicit drugs in their lifetime (Partnership for a Drug-Free America, 2005). Approximately 1 in 5 young persons (aged 12-17 years) use prescription pain-killers to get high, 1 in 11 abuse OTC products, and 1 in 10 had used CNS stimulants non-medically; About 1- 2% of secondary school students in 2009 reported non-medical use of methadone or anabolic steroids in the past year (Johnston et al., 2009). Further, on prevalence level by age groups, 6.3% of young adults aged 18-25 years, and 2.1% of young adults aged 26 and older report non-medical use of prescription drugs in the past month (SAMHSA, 2010b). Although, most literature on substance abuse in older adults (aged 50 and above) have focused on alcohol abuse, abuse of prescription and OTC drugs is more common in this age-group (Widlitz and Marin, 2002). Approximately, 4.3 million older adults (5% of adults in this age-group) used illicit drugs in the past year, of these 33% abused prescription-type drugs only (SAMHSA, 2009) <sup>[10]</sup>.

### **Short-term effects**

Impaired judgment, nausea, loss of coordination, headache, vomiting, loss of consciousness, numbness of fingers and toes, abdominal pain, irregular heartbeat, aches, seizures, panic attacks, psychosis, euphoria, cold flashes, dizziness, and diarrhea <sup>[11]</sup>.

### **Long-term effects**

Addiction, restlessness, insomnia, high-blood pressure, coma or even death occur <sup>[10]</sup>.

### **Risks of Self-Care/Self-Medication**

Although an OTC product becomes available without a prescription because of a compatible safety profile, its use will not be devoid of all risk. Such risks could include incorrect self-diagnosis, incorrect choice of therapy, incorrect dosage, occurrence of side effects, drug interactions and so on. Improper use is a major problem with OTC consumption. One U.S. survey showed that 33 percent of American adults (extrapolated to be 64 million) took more than the recommended dose of OTC drugs. Of these individuals, almost seven in ten (69 percent)

admitted to taking more than the recommended amount at a single time; 63 percent took the next dose sooner than directed and 44 percent ingested more than the recommended number of doses per day. The findings also suggested that 91 percent of respondents using higher than the recommended dosages thought it would increase the effectiveness of the drug. According to results from a national Canadian survey of similar design, the situation of incorrect OTC use seems better than that seen for American citizens, but still of concern. Fifteen percent of Canadian adults stated taking more than the number of recommended doses for a day. It was estimated that nearly five million adults take the next dose of their OTC products sooner than directed on the label. Even though OTC medicines are generally safe, they still have side effects. Caranasos et al found that 18 percent of all hospitalizations resulted from adverse reactions caused by OTC drugs during a three-year period.<sup>144</sup> Litovitz and Manoguerra determined that from 1985 to 1989, about 670,000 reports related to adverse effects and overdoses were received by poison control centers in children younger than 6 years old.<sup>145</sup> These cases included analgesics, cough/cold remedies, and gastrointestinal products. The potential for OTC medicine-disease interaction may be underestimated by OTC users. For instance, 70 percent of hypertensive patients surveyed had taken an OTC product during the previous two weeks, while less than 20 percent of these same individuals were aware that some OTCs could influence their blood pressure. Similarly, non-steroidal anti-inflammatory drugs (NSAIDs) can potentially exacerbate the symptoms of asthma. However, one-third of asthmatic patients interviewed by Lamb et al still took aspirin or NSAIDs to treat some minor ailments. Only 27 percent of the asthmatic patients who bought OTCs would think of informing the pharmacist that they had asthma. Prescription-OTC drug interactions exist and OTC users need to realize the potential for their occurrence. In a paper on the frequency of daily OTC drug use and clinically significant OTC-prescription drug interactions in the Finnish adult population, Sihvo et al determined that 4 percent of OTC users (on average) may be potentially hurt by those interactions. The paper highlighted the potential for interactions with ketoprofen, followed by ibuprofen and acetylsalicylic acid (ASA). Two studies by Honig and Gillespie found that many OTC drugs has the potential for clinically significant interactions with other drugs. Their examples of potentially problematic OTC groups were antacids, H2-blockers, salicylates, NSAIDs, cough/cold/allergy remedies, and anti-asthma products. The continuous use of OTCs, the number of OTC medicines used, and the number of prescription drugs raise the risks for adverse interactions. For perspective, Andreasen and Damsgaard determined that the subjects of their study took on average 4.2 different prescription drugs and 2.5 OTC medicines. Batty et al found that 32 percent of in-patients aged 65 years and over continually used OTC medicines during hospital admission<sup>[12]</sup>.

#### **Over the counter drugs in Bangladesh**

In a community study we found that 94% of the population took drugs without prescription, the commonest being paracetamol and various nonsteroidal anti-inflammatory drugs (87%); metronidazole (51%); antacids and ranitidine (59%); vitamins and iron (45%); antibiotics (31%); and sedatives, tranquillisers, and antidepressants (28%). Most took the drugs because they thought that they knew the treatment for their condition, but they were unaware of the risks of non-steroidal anti-inflammatory drugs and antibiotics, for example. The non-availability of a doctor and the lack of legal restrictions on the sale of the drug without prescription were not the

main reasons for them taking the drug. A recent survey in several districts of Bangladesh showed that 105 people died of perforation of a peptic ulcer and several thousand suffered from peptic ulceration after injudicious consumption of non-steroidal anti-inflammatory drugs.<sup>2</sup> A national drug policy based on the World Health Organisation's essential drug programme has been effective in Sri Lanka.<sup>3</sup> Such a policy has been implemented in Bangladesh, but the situation here has yet to improve owing to lack of awareness in the community<sup>[13]</sup>. India is witnessing an enhanced in abuse of prescription drugs and over-the-counter pharmaceutical preparations which contain psychotropic substances, according to a report by an international narcotics control body (INCB). "South Asia is experiencing increasing problems related to the abuse of and trafficking in prescription drugs and over-the-counter pharmaceutical preparations containing narcotic drugs and psychotropic substances," the International Narcotics Control Board (INCB) said in its annual report for 2011. It said that their low cost, high profit margin and easy availability, as well as the misperception that they are less harmful than illicitly manufactured drugs, are the main reasons for the increasing abuse and trafficking. The report noted "rise" in trafficking in pharmaceutical preparations containing narcotic drugs. In a worrying trend, the report noted increase in the HIV and Hepatitis C infection rates due to drugs abuse through injections. The abuse of drugs by injection is increasing in South Asia and has reached significant proportions in Bangladesh, India and Nepal. Drugs abused by injection in the region include heroin, prescription opioids and mixtures with other controlled substances. The abuse of drugs by injection has contributed to an increase in the HIV and hepatitis C infection rates," the report made by INCB(International Narcotics Control Body)., which acts as independent monitoring body for the implementation of the United Nations international drug control conventions, said. Bangladesh and India continue to be used by transnational organized criminal groups to divert precursors of amphetamine-type stimulants, because of the wide availability of the precursor's ephedrine and pseudoephedrine in those countries," it said. The INCB has urged the government to strengthen measures to ensure pharmacies comply with prescription requirements and to "ensure that over-the-counter pharmaceutical preparations are not diverted to be used for non-medical purposes" <sup>[14]</sup>.

### **Conclusion**

If we do not consider proper use of OTC drugs it may initiate several causes of diseases. Irrelevant uses of OTC drugs promote permanent chronic diseases. So OTC drugs should be controlled and properly.

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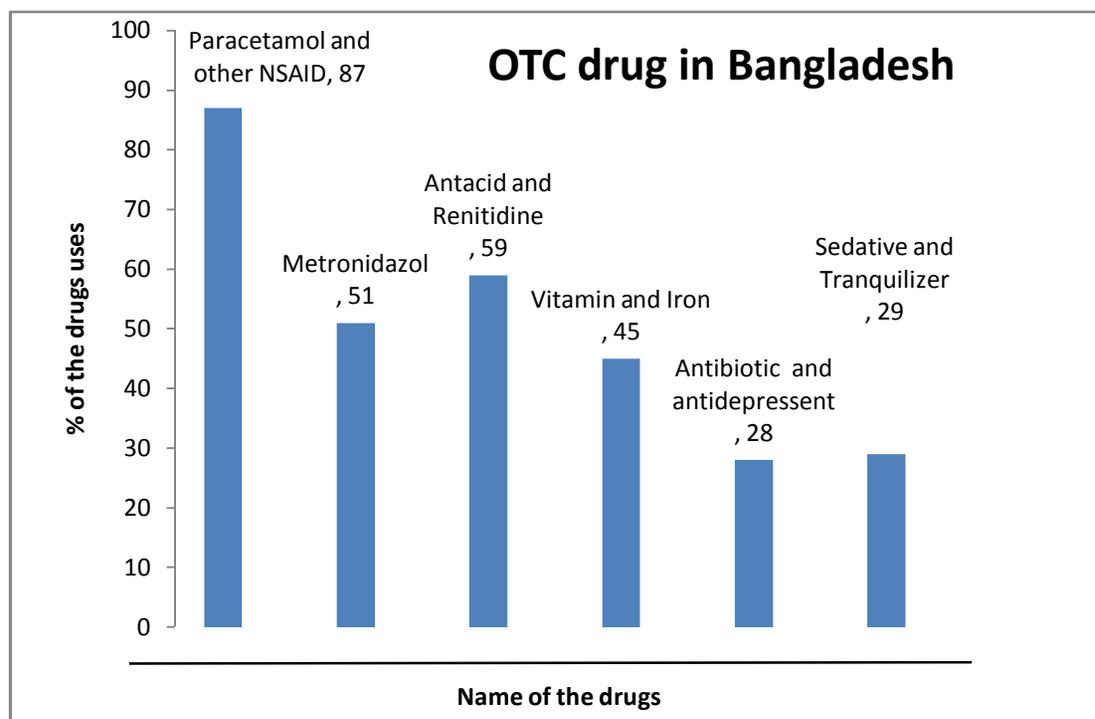


Fig2: OTC Drugs used in Bangladesh.

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