



Avoiding Adverse Drug Effects

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Drugs are used to treat disease and illness, and many of them reduce symptoms and save lives. Adverse effects are undesirable and sometimes harmful results from drugs or other therapies. While the beneficial effects of drugs are demonstrated in clinical trials, their adverse effects are less well known and may not become fully evident for years after their approval for clinical use. To understand adverse effects we must first understand what is a drug, how it normally works, and why even to most beneficial drugs may cause harm.

What is a Drug?

A drug is any substance that, when absorbed into a living organism, alters normal bodily function. There are three broad categories of drugs used to treat illness and disease:

- Prescription drugs
- Over-the-counter drugs
- Alternative remedies

Prescription drugs are those approved by regulatory authorities such as the Food and Drug Administration (FDA) in the U.S. and the European Medicines Agency (EMA) in the European Union. To achieve regulatory approval, drug manufacturers must prove that the candidate drug is effective and safe. This usually means the drug is validated by a randomized clinical trial (RCT). These products are only available by prescription. An example is penicillin.

A clinical trial or clinical study (they mean the same thing) is a research study to answer specific questions about new products, therapies, or new ways of using known treatments. A randomized clinical trial (RCT) is a study in which people are allocated at random to receive one of several clinical interventions including a standard of comparison or control.

Over-the-counter (OTC) drugs are those available, usually in drug stores or pharmacies, without a prescription. Many of these have not been tested by a randomized clinical trial, and were available before any drugs were regulated. An example is aspirin (acetylsalicylic acid). Others formerly were prescription drugs but are now deemed safe enough

to be sold OTC. Examples are H2 receptor antagonists such as ranitidine or cimetidine used for heartburn.

The third category of therapy drug consists of alternative treatments such as herbal remedies. This article refers mainly to prescription drugs, but applies to all categories, for OTC and herbal medicines may also cause serious adverse reactions.

How do Drugs Work?

The modes of action of individual drugs are diverse. Usually a small part of the drug molecule acts on a specific receptor on the cell that serves a certain bodily function, such as transmission of a nerve or hormonal message. The drug may facilitate the transmission (agonist) or inhibit it (antagonist). Examples of the latter are the H2 receptor antagonists, which block one pathway that promotes stomach acid secretion.

Other drugs are not targeted at the body at all, but rather at invasive microorganisms. An example of such antimicrobial agents is penicillin. It is an antibiotic that works by damaging the wall or membrane of a susceptible bacterium's cell. Antiviral, antifungal, and anti-parasitic drugs are in this category.

Vitamins act as co-enzymes facilitating certain bodily functions. For example, vitamin D acts on bones and body calcium metabolism. Sunlight facilitates vitamin D synthesis and supplementation of this vitamin is deemed essential in northern climes, where sun exposure is limited. Other drugs act by changing the body's internal or external environment. For example, antacids such as calcium carbonate neutralize stomach acid and relieve heartburn, and osmotic laxatives attract water into the gut promoting more easily passed stools.

Why do Adverse Effects Occur?

What these and other drug actions have in common is the potential to do harm. The effective part of most drug molecules is small, and may not be specific for the targeted receptor. For example, the non steroidal anti-inflammatory drugs (NSAIDs) act to reduce mediators of inflammation in joints or elsewhere. While this relieves joint pain in

arthritis, it also interferes with the stomach's ability to resist the damaging effects of gastric acid and may cause peptic ulcers. The molecular configuration of antimicrobial agents may damage human tissue. Any foreign molecule may unpredictably affect receptors other than the target prompting a reaction or, more commonly, set up an immune response, which we call a drug allergy. This usually manifests as skin rash or kidney damage.

While a little vitamin is essential to health, excess is harmful. Too much vitamin D can elevate blood calcium resulting in heart and kidney damage. Laxatives and antacids may have adverse effects if given in excess by interfering with the absorption of nutrients and other drugs. Sometimes drugs interact with one another, an example being when one drug alters the liver enzyme required to metabolize another. Antibiotics have many potentially adverse effects that include the production of antibiotic resistant organisms or the alteration of friendly intestinal bacteria to permit overgrowth of harmful bacteria.

It is important to know that the diverse list of potentially adverse effects applies to all drugs, even those sold OTC. Familiar pain-relievers such as aspirin and acetaminophen, if not carefully used can cause stomach bleeding and liver damage respectively.

How Should you Prevent Adverse Effects?

It is wise to assume that no drug, even an OTC or herbal medicine, is completely without adverse effects. The first rule is to resist consuming a drug unless it's necessary. Advertisements about the virtues of drugs are widespread, the object being to sell more drugs. Here are some questions to consider:

- Are the benefits supported by medical evidence such as that obtained by randomized clinical trials?
- Do the purported benefits apply to you now?
- Is your illness or disease severe or threatening enough to justify any risk?
- Is your condition chronic so that drug exposure will be necessary for a long time?
- How serious are the possible adverse effects (e.g. transient nausea versus kidney failure)?
- Are there other measures such as diet or exercise that may reduce the need for the drug?
- What is the lowest dose that benefits you, and can you stop the drug periodically? (Except for allergic reactions, most adverse reactions are greater the higher the dose and the longer the exposure.)
- Is there another drug that treats your condition with a safer profile?

- Are there things you can do to minimize the risks?

Sometimes an adverse effect is unavoidable to achieve the drug's benefits. In these cases, patients must put up with unwanted effects to fulfill the drug's promise. Ask your doctor what might be expected, what to look out for, and what to do if side effects do occur.

Labeling

Drug regulatory agencies must approve prescription drugs and require detailed labeling of their products. The container and product labels should precisely state the purpose and effectiveness of the drug and detail its known and potential side effects. Careful review of these should help you decide if the potential benefit of the drug justifies the possible risk. It is complicated. With any drug, not all patients benefit, and in most cases few suffer adverse effects. After reading the documentation it may help to have your doctor or pharmacist put the risks into perspective for you.

Depending upon the jurisdiction, labeling of OTC medicines is less satisfactory. Because many such drugs have been around for many decades, they have not been subject to regulatory scrutiny as have prescription drugs. As with any drug, the wise consumer will study the label, and not exceed the recommended dose. If a little of a drug helps, it does not follow that a bigger amount will be better. Drug allergies, lethal overdoses, and adverse gut effects in particular are far too frequent with these common products. Particular care is necessary when selecting pain and sedating medication. Combination OTC products often contain potentially dangerous drugs such as aspirin or acetaminophen that are not noticed by unwary consumers.

Many herbal medicines are claimed to be safe, and critics claim that is because often they have no effect at all. However, some have ingredients that act as described above and have the potential to do harm. Some cause liver failure and others allergies. Others may have a mild benefit but adversely interact with another drug. The potential problems are many. In most jurisdictions these products are poorly or not-at-all regulated. Too often the supposed active ingredient, mode of action, and actual chemical make-up of these purported remedies are unknown and since they are biological products, their concentration may vary from batch to batch. Fortunately, alternative medications are coming under increasing scientific scrutiny and regulation. Meanwhile, they deserve all the precautions called for when selecting a prescription drug.

Conclusion

Adverse drug reactions comprise a vast scientific body of knowledge and continuing research that can only be touched upon here. Such reactions are widespread and few if any drugs are completely free of risk. Drugs may act adversely in many ways. Before undertaking any drug therapy, you should carefully read the available information, discuss it with a health professional, and try to weigh the seriousness of your complaint and the likelihood of a drug's benefit against the risks (likelihood and seriousness) of an adverse event. When used properly, drugs are a great benefit to mankind – when not, tragedies await.

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