Introduction to Nursing Pharmacology

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Introduction to Drugs

KEY TERMS
adverse effects
biopharmaceutical
British National Formulary
chemical name
concordance
drugs
generic drugs
generic name
genetic engineering
Medicines and Healthcare products Regulatory Agency (MHRA)
mutagenic
National Institute for Health and Clinical Excellence (NICE)
over-the-counter (OTC) drugs
pharmacodynamics
pharmacokinetics
pharmacology
pharmacotherapeutics
phase I studies
phase II studies
phase III studies
phase IV studies
placebo
preclinical tests
teratogen
trade name

LEARNING OBJECTIVES
Upon completion of this chapter, you will be able to:
1. List the standards set by the Nursing and Midwifery Council for the management and administration of drugs.
2. Define the word pharmacology.
3. Outline the steps involved in developing and approving a new drug in the United Kingdom.
4. Describe the controls on drugs that have abuse potential.
5. Differentiate between generic and trade name drugs, over-the-counter drugs and prescription drugs.
6. Explain the benefits and risks associated with the use of over-the-counter drugs.
The human body functions through a complicated series of chemical reactions and processes. Drugs are chemicals that are introduced into the body to cause a biological effect. When drugs are administered, there are a sequence of processes that handle the new chemicals including the breakdown and elimination of the drugs from the body.

For many reasons, understanding how drugs act on the body to cause changes and applying that knowledge in the clinical setting are important aspects of nursing practice. For example, patients often follow complicated drug regimens and receive potentially toxic drugs. In addition, some drugs interact with other drugs and some foodstuffs. Many patients also manage their own care at home. Therefore, the nurse is in a unique position regarding drug therapy because nursing responsibilities include the following:

- Administering drugs
- Assessing drug effects
- Intervening to make the drug regimen more tolerable
- Providing patient teaching about drugs and the drug regimen
- Monitoring the overall patient care plan to prevent medication errors.

Understanding the mechanism of action of drugs makes these tasks easier to handle, thus enhancing drug therapy and ultimately patient concordance.

This text is designed to provide the pharmacological basis for understanding drug therapy. The physiology of a body system and the related actions of many drugs on that system are presented in a way that allows clear understanding of how drugs work and what to anticipate when giving a particular type of drug. Thousands of drugs are available for use, and it is impossible to memorize all of the individual differences among drugs in a class. However, it is important to know and understand the most common drugs prescribed and administered on a daily basis. When using unfamiliar drugs, the nurse should first seek out the relevant information [e.g. from the British National Formulary (BNF)] prior to drug administration.

- Be certain of the identity of the patient to whom the medicine is to be administered.
- Check that the patient is not allergic to the medicine before administering it.
- Know the therapeutic uses of the medicine to be administered, its normal dosage, side-effects, precautions and contraindications.
- Be aware of the patient’s plan of care (care plan/pathway).
- Check that the prescription or the label on the medicine dispensed is clearly written and unambiguous.
- Check the expiry date (where it exists) of the medicine to be administered.
- Have considered the dosage, weight where appropriate, method of administration, route and timing.
- Administer or withhold in the context of the patient’s condition (e.g. digoxin not usually to be given if the pulse is below 60 beats per minute) and coexisting therapies (e.g. physiotherapy).
- Contact the prescriber or another authorized prescriber without delay where contraindications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable.
- Make a clear, accurate and immediate record of all medicines administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible; it is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

In addition:

- Where medication is not given the reason for not doing so must be recorded.
- You may administer with a single signature any Prescription Only Medicine (POM), General Sales List (GSL) or Pharmacy (P) medication.

(Taken from Standards for Medicines Management, 2008).

It is important to remember that nurses are legally and professionally responsible for any error that might occur.

In the past, the role of nurses in prescribing has been restricted to community nurses who were allowed to prescribe from a limited range of medicines, and appliances and dressings. However, from May 2006 the government permitted all nurses who had completed the relevant nurse prescribers’ course and assessments to become Nurse Independent Prescribers. These qualified nurses are permitted to prescribe any licensed medicine within their competence; this includes some controlled drugs for use in palliative care, for example. The prescribing responsibilities of nurses are dependent on where the nurse is currently working. For example, the responsibilities of a nurse working in England may vary from the responsibilities of a nurse working in Scotland, Wales or Northern Ireland.
Nurses should have a clear understanding of how the responsibilities have been implemented in their country.

Pharmacology

**Pharmacology** is the study of the biological effects of chemicals administered to a living organism. Nurses deal with **pharmacotherapeutics**, or clinical pharmacology, the branch of pharmacology that uses drugs to treat, prevent and diagnose disease. Clinical pharmacology addresses two key concerns: the effect(s) of the drug on the body (pharmacodynamics) and the way in which the body handles the drug (pharmacokinetics).

A drug can have many effects; therefore, the nurse must know which ones may occur when a particular drug is administered. Most of these effects are therapeutic, or helpful, whereas others can be undesirable or potentially dangerous and are known as **adverse effects** (see Chapter 3 for a detailed discussion of adverse effects).

Sources of Drugs

Drugs are available from varied sources, both natural (e.g. plants, fungi, animals or inorganic compounds) and synthetic.

**Plant Products**

Plants and plant extracts have been used as medicines for many centuries. Even today, plants are an important source of chemicals that are developed into drugs. For example, digitalis products from *Digitalis purpurea* (foxglove plant) used to treat cardiac disorders; opiates such as morphine, codeine and papaverine from *Papaver somniferum* (opium poppy); and the taxanes derived from the bark of *Taxus brevifolia* (yew trees) are used in cancer chemotherapy. Plant extracts have also become the main component of the growing alternative therapy movement.

**Fungi**

The most well-known example of a drug derived from fungi is the antibiotic penicillin used to treat a number of communicable diseases. Penicillin and other β-lactam antibiotics are derived from the mould *Penicillium chrysogenum*. The immunosuppressant drug, ciclosporin, used to reduce the activity of a patient’s immune system following organ transplantation, was also originally derived from a fungus.

**Animal Products**

Animal products are used to replace human chemicals that are not produced because of disease or genetic problems. Until 1982, insulin for treating diabetes was obtained exclusively from the pancreas of cows and pigs. Now **genetic engineering**, the process of altering deoxyribonucleic acid (DNA), permits scientists to produce human insulin by altering *Escherichia coli* bacteria, making insulin without some of the impurities that come with animal products. The insulin produced using genetic engineering procedures is known as a **biopharmaceutical**, a protein or nucleic acid prepared using genetic engineering technology.

Inorganic Compounds

Salts of various elements can have therapeutic effects in the human body. Aluminium, fluoride, lithium, iron and even gold are used to treat various conditions. The effects of these elements were usually discovered accidentally when a cause–effect relationship was observed. Table 1.1 shows examples of some elements used for their therapeutic benefit.

### Table 1.1 Elements Used for Their Therapeutic Effects

<table>
<thead>
<tr>
<th>Element</th>
<th>Therapeutic Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium</td>
<td>Antacid to decrease gastric acidity, Management of hyperphosphataemia, Prevention of the formation of phosphate urinary stones</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Prevention of dental cavities, Prevention of osteoporosis</td>
</tr>
<tr>
<td>Gold</td>
<td>Treatment of rheumatoid arthritis</td>
</tr>
<tr>
<td>Iron</td>
<td>Treatment of iron deficiency anaemia</td>
</tr>
<tr>
<td>Lithium</td>
<td>Treatment of mania</td>
</tr>
</tbody>
</table>

Synthetic Sources

Even today, many drugs are developed from chemicals in plants, animals or the environment that have been screened for signs of therapeutic activity. Most new drugs are purely synthetic. Technical advances allow scientists to alter a chemical with proven therapeutic effectiveness to make it better. Sometimes, a small change in a chemical’s structure can make that chemical more useful as a drug – more potent, more stable, less toxic. These technological advances have led to the development of groups of similar drugs, all of which are derived from an original prototype, but each of which has slightly different properties, making a particular drug more desirable in a specific situation.

**Biopharmaceuticals**

As mentioned above, biopharmaceuticals are proteins (including antibodies) or nucleic acids produced by genetic engineering for therapeutic purposes. There is a large range of biopharmaceuticals, including thrombolytic agents such as tissue plasminogen activator; hormones (insulin, growth hormone); vaccines; interferons used in the treatment of leukaemia and multiple sclerosis; and also monoclonal antibodies, such as trastuzumab (Herceptin), used to target specific proteins on cancer cells.
Drug Evaluation

To become a drug, a chemical must have demonstrated therapeutic value or efficacy without severe toxicity or damaging properties. Once a chemical that might have therapeutic value is identified, it must undergo a series of tests to evaluate its actual therapeutic and toxic effects. The need for extensive testing was reinforced by the ‘thalidomide disaster’ in the early 1960s. The hypnotic drug thalidomide was regarded as suitable for use during pregnancy. However, the drug had not been tested on pregnant animals and was subsequently found to be a potent teratogen (i.e., causing adverse effects on the foetus). This resulted in more than 10,000 children born with severe malformations.

This process of evaluation significantly reduces the number of potential drugs that actually make it to the end stage: for every 5000 chemicals that are identified as being potential drugs, only one will become an approved drug. Before receiving final approval for marketing to the public, drugs must pass through preclinical tests on animals and phase I, II and III studies on humans. Figure 1.1 highlights the various phases of drug development.

Preclinical Tests

In preclinical tests, chemicals that may have therapeutic value are tested on cell cultures and laboratory animals. Whole animal testing is an important part of the drug development process; however, there is significant public opposition to the use of animals in experiments. A comment often quoted is that the physiological processes animals undergo are so different from our own. Although there are recognized differences in the way humans and laboratory animals (e.g., rats, rabbits) metabolize drugs (Berthou et al., 1992) for example, these differences are far outweighed by the similarities between species (Research Defence Society, 2009). It should also be recognized that the number of experiments using live animals has decreased by over 35% in the past 30 years (Home Office, 2009).

Preclinical tests have several purposes:

- To assess if they are likely to have beneficial effects in models of disease.
- To evaluate any toxic effects in the short and long term.
- To assess their teratogenic and mutagenic effects, that is their potential to cause adverse effects on the foetus and genetic material, respectively.
- To determine how the animal handles the drug: How is it absorbed? How is it metabolized? How long does it take to eliminate the drug from the body?

At the end of the preclinical testing, some chemicals are discarded for the following reasons:

- The chemical lacks therapeutic activity when used with living animals.
- The chemical is too toxic to living animals to be worth the risk of developing into drugs.
- The chemical is highly teratogenic or mutagenic.
- The safety margins are so small that the chemical would not be useful in the clinical setting.

**FIGURE 1.1.** Phases of drug development.
Some chemicals, however, are found to have therapeutic effects and acceptable safety margins. This means that the chemicals are therapeutic at doses that are reasonably different from doses that cause toxic effects. Such chemicals will pass the preclinical trials and advance to phase I studies.

**Phase I Studies**

*Phase I studies* are the first occasion where the drug is tested on humans and the aim is safety evaluation not effectiveness in disease control. Permission to enter phase I studies must be granted by the local ethics committee and also the National Drug Regulatory Authority. The ethics committee will evaluate the risks to the volunteers, the process of recruiting volunteers, the experience of the clinical investigators and the design of the study. The regulatory authorities will determine if there is a scientific need to carry out the study. The overriding authority in control of this regulatory procedure is the Medicines and Healthcare products Regulatory Authority (MHRA).

In phase I studies small groups of between 40 and 60 individuals volunteer to test the drugs. These studies are performed by specially trained clinical investigators. The volunteers are fully informed of possible risks and are paid for expenses and for any inconvenience caused. Generally, the volunteers are healthy, young men. Women are not usually candidates for phase I studies because the chemicals may exert unknown and harmful effects on their ova. In addition, the cyclical changes in female hormones can add further complexity. However, some studies will recruit women provided they are using contraceptives, have produced a negative pregnancy test or are postmenopausal. Men produce sperm daily, so there is less potential for complete destruction or alteration of the sperm.

Single doses of the drug under test are given to the volunteers. Investigators obtain data on how the drug is absorbed, distributed, metabolized and excreted; the biological effects of the drug; adverse effects and toxicity and also the appropriate dosage for subsequent studies. At the end of phase I studies, many drugs are dropped from the process because they may cause unacceptable adverse effects. For example, if phase I studies are successful, then investigations move on to phase II studies.

**Phase II Studies**

*Phase II studies* are the first opportunity for clinical investigators to try the drug on patients who have the disease that the drug is designed to treat. Patients are told about the possible benefits of the drug and are invited to participate in the study. Those patients who consent to participate are fully informed about possible risks and are monitored very closely to evaluate the drug’s effects. Usually, phase II studies are performed at various sites across the country – in hospitals, clinics and GPs’ surgeries – and are monitored by representatives of the pharmaceutical company studying the drug. These studies provide information on the optimal dose and also the therapeutic potential of the drug. The therapeutic potential is often determined in comparison with a placebo, a substance or treatment the patient believes will have a therapeutic effect; or to the existing standard treatment.

At the end of phase II studies, a drug may be removed from further investigation for the following reasons:

- It is less effective than anticipated.
- It is too toxic when used with patients.
- It produces unacceptable adverse effects.
- It has a low benefit-to-risk ratio, meaning that the therapeutic benefit it provides does not outweigh the risk of potential adverse effects that it causes.
- It is no more effective than other drugs already on the market, making the cost of continued research and production less attractive to the drug company.

A drug that continues to show promise as a therapeutic agent receives additional scrutiny in phase III studies.

**Phase III Studies**

*Phase III studies* involve use of the drug in a larger patient group (250 to >1000 subjects) for a period of 2 to 5 years. As in phase II studies, the drug under test will be compared with either a placebo or an existing treatment.

The larger group size enables evaluation of the efficacy of the drug in patients from different groups, for example age, ethnicity, and others. Patients are observed very closely and monitored for any adverse effects. It is possible that more adverse effects are recorded from a wider sample of the patient population and following long-term drug administration. Prescribers sometimes ask patients to keep journals and record any symptoms they experience. Prescribers then evaluate the reported effects to determine whether they are caused by the disease or by the drug. This information is collected by the drug company that is developing the drug and is shared with the MHRA. A drug that produces unacceptable adverse effects or unforeseen reactions is usually removed from further study by the drug company. In some cases, the MHRA may have to request that a drug be withdrawn from the market.

**Final Drug Approval**

Drugs that successfully complete phase III studies are evaluated by regulatory authorities in the country where approval is sought. These authorities rely on committees of experts familiar with the specialty area in which the drugs will be used. Only those drugs that receive approval and are granted a product licence may be marketed.

These preclinical tests and clinical trials may take up to 12 years to complete, resulting in a so-called drug lag. However, public safety is paramount in drug approval, so the process remains strict. In certain instances involving the treatment of deadly diseases, the process can be accelerated. For example, efavirenz was thought to offer a benefit to patients with acquired immune deficiency syndrome (AIDS), a potentially fatal immune disorder; and was pushed through because of the progressive nature of AIDS and the lack of a cure. All literature associated with these drugs indicates that
Generic, Chemical and Trade Names of Drugs

1-(4-Chlorophenyl)-5-isopropylbiguanide hydrochloride ← Chemical name → 9α-Chloro-11β,17α,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate
Proguanil hydrochloride ← Generic name → Beclometasone dipropionate
Malarone ← Trade names → Beconase

Continual Evaluation

After a drug is approved for marketing, it enters a phase of continual evaluation or phase IV study. Prescribers are required to report any untoward or unexpected adverse effects associated with drugs they are using to the MHRA. The MHRA continually evaluates this information. Some drugs cause unexpected effects that are not seen until wide distribution occurs. Sometimes, those effects are therapeutic. For example, patients taking the antiparkinsonism drug amantadine were found to have fewer cases of influenza than other patients, leading to the discovery that amantadine is an effective antiviral agent.

In other instances, the unexpected effects are dangerous. In 1997, the diet drug dexfenfluramine was withdrawn from the market only months after its release because patients taking it developed serious heart problems. In 1998, the antihypertensive drug mibefradil was removed from the market not long after its release because patients taking it were found to have more cardiac morbidity. These problems were not seen in any of the premarket studies.

Licensed and Unlicensed Drugs

There are occasions when an unlicensed drug, that is a drug which has not completed the entire clinical trials programme, is used to treat a patient. For example, an unlicensed drug may be used as drug treatment as part of a clinical trial. Alternatively, the doctor may consider that the patient will benefit from the new treatment because other treatment approaches have failed. The doctor must apply to the pharmaceutical company to use the drug on what is known as a ‘named patient’ basis. The doctor takes responsibility for the unlicensed drug treatment and the patient must be made aware of the potential risks associated with the drug.

Drugs that have successfully passed through clinical testing are granted a product licence by the MHRA. This licence permits the pharmaceutical company to market this drug for the treatment of specific diseases or medical needs covered by the license. If it becomes apparent that the new drug could be useful in another clinical situation, for example to treat another form of cancer, the pharmaceutical company will need to conduct further clinical trials and obtain another license for the second condition. In the meantime, doctors can use this unlicensed form of the drug to treat a patient for an indication that is not covered by the original license. This is known as ‘off-label’ use.

The National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) was established in 1999 to provide guidance to health care professionals and also members of the public through the sharing of best practise. This organization provides information on three key areas: (1) promotion of good health and prevention of ill health; (2) new and existing medicines, treatments and procedures available within the National Health Service (NHS); and (3) the most suitable treatment for patients with specific diseases and conditions (NICE, 2008) to maximize resources by evaluating the cost to the NHS against the benefits to the patient. NICE uses current published evidence about the intervention to evaluate whether or not it would be cost effective for the NHS to use a particular medical intervention (e.g. the use of inhaled corticosteroids in the treatment of asthma for adults). When NICE recommends a specific medicine or treatment, the NHS is legally obliged to provide the funding.
Legal Regulation of Drugs

The Medicines Act (1968) controls the manufacture and supply of medicine. Newly marketed drugs can be allocated to one of four categories:

1. Prescription-only medicine controlled drugs (POM CD) can be supplied only by authorized individuals.
2. Prescription only medicine can be sold only by a pharmacist in receipt of a prescription from a doctor.
3. Pharmacy-only drugs (P) can be sold without the need of a prescription by pharmacists.
4. General sales list drugs can be sold without a prescription in any shop.

Controlled Substances

Drugs with abuse potential are called controlled substances. The Misuse of Drugs Act (1971) regulates the manufacturing, distribution, and possession of drugs that are known to have abuse potential. This act established categories for ranking the abuse potential of various drugs, where Class A drugs are considered to be the most harmful. Examples of drugs in each class include:

- Class A – ecstasy, lysergide (LSD), diamorphine (heroin), morphine, opium, pethidine, cocaine, crack, magic mushrooms, methylamphetamine (crystal meth) and other amphetamines if prepared for injection.
- Class B – oral amphetamines, barbiturates, codeine, pholcodine, ethylmorphine, glutethimide, pentazocine and phenmetrazine.
- Class C – drugs related to amphetamines, cannabis (including resin), most benzodiazepines and androgenic and anabolic steroids.

A second act, the Misuse of Drugs Regulations (2001) specifies those individuals who are authorized to supply drugs from these categories to their patients. The Home Office is responsible for the enforcement of these regulations.

Generic Drugs

When a pharmaceutical company has synthesized and carried out some preclinical testing it applies for a patent. A patent is usually valid for 20 years and only that company can sell the drug during that time. When the patent runs out on a trade name drug, the drug can be produced by other manufacturers. Generic drugs are medicines that are produced by companies that just manufacture drugs. These companies do not have the research or the advertising that pharmaceutical companies have and can, therefore, produce the generic drugs more cheaply. In the past, some quality control problems were found with generic products. For example, the binders used in a generic drug might not be the same as those used in the trade name product; as a result, the way the body absorbs and uses the drug may differ. In that case, the bioavailability of the drug is different from that of the trade name product.

Many hospital trusts require that a drug be dispensed in the generic form if one is available. This requirement helps keep down the cost of drugs and healthcare. Some prescribers, however, specify that a drug prescription be ‘dispensed as written’; that is, the trade name product be used. By doing so, the prescriber ensures the quality control and bioavailability expected with that drug. These elements are particularly important in drugs that have narrow safety margins, such as digoxin, a heart drug, and warfarin, an anticoagulant. The initial cost may be higher, but some prescribers believe that, in the long run, the cost to the patient will be less.

Over-the-Counter Drugs

Over-the-counter (OTC) drugs are products that are available without prescription for self-treatment of a variety of complaints. Some of these agents were approved as prescription drugs but were later found to be very safe and useful for patients without the need of a prescription. Although OTC drugs have been found to be safe when taken as directed, nurses should consider several problems related to OTC drug use:

- Taking these drugs could mask the signs and symptoms of underlying disease, making diagnosis difficult.
- Taking these drugs with prescription medications could result in drug interactions and interfere with drug therapy.
- Not taking these drugs as directed could result in serious overdoses.

Many patients do not consider OTC drugs to be medications and, therefore, do not report their use. Nurses should always include specific questions about OTC drug use when taking a drug history and should provide information in all drug-teaching protocols about avoiding OTC use while taking prescription drugs.

Sources of Drug Information

The fields of pharmacology and drug therapy change so quickly that it is important to have access to sources of information about drug doses, therapeutic and adverse effects and nursing-related implications. This text addresses general drug information and provides valuable background and basic information to help in the understanding of pharmacology, but in clinical practice it is important to have access to up-to-the-minute information. Several sources of drug information are readily available.
The British National Formulary

The nurse must refer to the latest edition of the BNF to obtain the specific details required for safe and effective drug administration. Updated on a 6-monthly basis, the BNF provides an up-to-date and comprehensive drug guide for use by prescribers and other health care professionals in the clinical setting. The BNF is also available on the Internet. The prescriber is provided with details of:

- **Indications**, that is the disease(s) the drug is approved to treat.
- **Contraindications**, that is those individuals where taking a specific drug could affect a pre-existing medical condition.
- **Cautions**, where taking the drug could increase the risk of unwanted effects in certain patients, for example those patients who are pregnant or have diabetes.
- **Interactions** lists the possible interactions with any medicines the patients may be taking.
- **Side-effects** include the side-effects observed in patients taking this drug.
- **Costs** of all of the drugs available on the NHS.

The BNF for Children provides equivalent information on medicines approved for children.

Package Inserts

All drugs come with a package insert prepared by the manufacturer according to regulations laid down by the regulatory authorities. The package insert contains information for patients on:

- what the medicine is,
- how the medicine works,
- the infections/diseases the medicine can be used to treat,
- cautions to patients regarding pre-existing conditions or potential interactions with other medicines,
- how to administer the medicine together with any possible cautions to be taken into consideration, for example do not wear contact lenses while you are using an antibacterial treatment for conjunctivitis,
- possible side-effects,
- how to store the medicine.

Nurses should encourage their patients to read these inserts before commencing treatment.

Publications

- The *Journal of Advanced Nursing* is an international, peer-reviewed, scientific journal. The published articles aim to advance knowledge in a number of areas, including practice, education, management and policy.
- The *British Journal of Nursing* is a peer-reviewed scientific journal published fortnightly. The evidence-based articles are written by nurses and provide practical recommendations.

| Drug Safety Update | is a monthly newsletter from the MHRA and the Commission on Human Medicines (CHM). This newsletter provides updated information on specific medicines and key points on studies of the safety of medicines.
| Nursing Times | is published on a weekly basis and provides information on research studies and clinical articles to nurses at all levels, including those in training.

Internet Information

There are many Internet sites available for obtaining drug information, patient information or therapeutic information related to specific disease states. Many members of the public now use the Internet as a source of medical information and advice. It is a good idea for the nurse to become familiar with what is available on the Internet and what patients may be referencing. Information presented on Internet sites is less likely to be peer-reviewed and therefore the accuracy of the information must be questioned.

In each chapter the reader is guided towards appropriate and reliable Internet sites related to the chapter content.

**WEB LINKS**

- Health care providers may want to consult the following Internet sources:
  - [http://cks.library.nhs.uk](http://cks.library.nhs.uk) The NHS Clinical Knowledge Summaries provides evidence-based practical information on the common conditions observed in primary care.
  - [http://www.bnf.org.uk](http://www.bnf.org.uk) The BNF provides UK health care professionals with authoritative and practical information on the selection and clinical use of medicines.
  - [http://www.dh.gov.uk](http://www.dh.gov.uk) The Department of Health site provides information on many areas to health care professionals.
  - [http://www.direct.gov.uk](http://www.direct.gov.uk) The information on medical rules for all drivers can be found here (originally found under Driver and Vehicle Licensing Agency site).
  - [http://www.hpa.org.uk](http://www.hpa.org.uk) The Health Protection Agency provides support and advice on public health issues to the NHS and other authorities.
  - [http://www.mhra.gov.uk](http://www.mhra.gov.uk) The MHRA are an agency of the Department of Health and are responsible for ensuring that medicines and medical devices are safe for the public.
http://www.nhsdirect.nhs.uk The NHS Direct service provides patients with information and advice about health, illness and health services.

http://www.nice.org.uk The National Institute for Health and Clinical Excellence provides guidance on public health, new and existing treatments within the NHS and also information on the most appropriate care for patients.

http://www.nmc-uk.org The Nursing and Midwifery Council sets standards for training and education and ensures that those standards are maintained.

http://www.travax.nhs.uk This database provides travel health information for health care providers. This site can be accessed only by registered NHS users.

http://www.understandinganimalresearch.org.uk This site for the Research Defence Society provides information on the use of animals in research.

http://www.yellowcard.gov.uk Health care professionals and the public are encouraged to report unwanted or unexpected adverse reactions using the yellow card system.

Points to Remember

- All nurses must abide by the standards set by the Nursing and Midwifery Council for the safe administration of drugs.

- Drugs are chemicals that are introduced into the body to bring about some sort of change.
- Drugs can come from many sources: plants, animals, inorganic elements, synthetic preparations and biopharmaceuticals.
- Preclinical testing of potential drugs involves the use of laboratory animals to determine their therapeutic and adverse effects.
- Phase I studies test potential drugs on healthy human subjects to assess safety.
- Phase II studies test potential drugs on patients who have the disease the drugs are designed to treat.
- Phase III studies test drugs in the clinical setting to determine any unanticipated effects or lack of effectiveness.
- Phase IV studies assess the safety and efficacy of the newly approved drug on a wider population.
- The MHRA regulates the development and marketing of drugs to ensure safety and efficacy.
- Generic drugs are sold under their chemical names, not trade names; they may be cheaper but are not necessarily as safe as trade name drugs. OTC drugs are available without prescription for the self-treatment of various complaints.

Answers to the questions in this chapter may be found in the answer key in the back of the book.

Multiple Choice

Select the most appropriate answer to the following.

1. Clinical pharmacology is the study of
   a. the biological effects of chemicals.
   b. drugs used to treat, prevent or diagnose disease.
   c. plant components that can be used as medicines.
   d. binders and other vehicles for delivering medication.

2. Phase I drug studies involve
   a. the use of laboratory animals to test chemicals.
   b. patients with the disease the drug is designed to treat.
   c. mass marketing surveys of drug effects in large numbers of people.
   d. healthy human volunteers.

3. The generic name of a drug is
   a. the name assigned to the drug by the pharmaceutical company developing it.
   b. the chemical name of the drug based on its chemical structure.
   c. the original name assigned to the drug at the beginning of the evaluation process.
   d. often used in advertising campaigns.

4. The storing, prescribing and distributing of controlled substances – drugs that are more apt to be addictive – are monitored by the
   a. NICE.
   b. Department of Health.
   c. Committee for the Safety of Medicines.
   d. Home Office.

5. Healthy young women are generally not involved in phase I studies of drugs because
   a. male bodies are more predictable and responsive to chemicals.
   b. females are more apt to suffer problems with ova, which are formed before birth and not formed in later years.
   c. males can tolerate the unknown adverse effects of many drugs better than females.
   d. there are no standards to use to evaluate the female response.
6. A patient has been taking fluoxetine for several years, but when picking up the prescription this month, found that the tablets looked different and became concerned. The nurse, checking with the pharmacist, found that fluoxetine had just become available in the generic form and the prescription had been filled with the generic product. The nurse should tell the patient that
a. the new tablet may not work and the patient should carefully monitor response.
b. generic drugs are available without a prescription because they are very safe.
c. the law requires that prescriptions be filled with the generic form if one is available to cut down the cost of medications.
d. the pharmacist filled the prescription with the wrong drug and it should be returned to the pharmacy for a refund.

Extended Matching Questions

Select all that apply.

1. When teaching a patient about OTC drugs, which points should the nurse include?
   a. These drugs are very safe and can be used freely to relieve your complaints.
   b. These compounds are called drugs, but they aren’t really drugs and don’t need to be reported to your health care provider.
   c. Some of these drugs were once prescription drugs, but are now thought to be safe when used as directed.
   d. Reading the label of these drugs is very important; the active ingredient is very prominent; you should always check the ingredient name.
   e. It is important to read the label to see what the recommended dose of the drug is; some of these drugs can cause serious problems if too much of the drug is taken.
   f. It is important to report the use of any OTC drug to your physician, because many of them can interact with drugs that might be prescribed for you.
   g. It is important to check an OTC medication with the pharmacist if you are taking other medication.

2. A patient asks what generic drugs are and if he should be using them to treat his infection. Which of the following statements should be included in the nurse’s explanation?
   a. A generic drug is a drug that is sold by the name of the ingredient, not by trade name.
   b. Generic drugs are always the best drugs to use because they are never any different from the familiar trade names.
   c. Generic drugs are not available until the patent expires on a specific drug.
   d. Generic drugs are usually cheaper than the well-known trade names.
   e. Generic drugs are forms of a drug that are available over the counter and do not require a prescription.
   f. Your physician may want you to have the trade name of a drug, not the generic form, and DAW, or ‘dispense as written’, will be on your prescription.
   g. Generic drugs are less likely to cause adverse effects than trade name drugs.

Matching

Match the word with the appropriate definition.

1. ______________ generic engineering
2. ______________ MHRA
3. ______________ pharmacology
4. ______________ phase I study
5. ______________ OTC drugs
6. ______________ preclinical study
7. ______________ teratogenic
8. ______________ pharmacotherapeutics
9. ______________ generic drugs
10. ______________ drugs

A. The study of the actions of chemicals on living organisms
B. Medicines that can be produced by any pharmaceutical company once the drug’s patent has expired
C. Having adverse effects on the foetus
D. Chemicals that are introduced into the body to bring about some sort of change
E. A drug that is available without a prescription
F. Regulatory authority responsible for the evaluation and monitoring of new and existing medicines
G. Process of altering DNA to produce a chemical to be used as a drug
H. Initial study of a potential drug conducted with a small number of selected, healthy human volunteers
I. Initial trial of a chemical believed to have therapeutic potential; uses laboratory animals, not human subjects
J. Clinical pharmacology, the branch of pharmacology that deals with drugs

Bibliography and References

