

GCSE key words  
Testing medicines



*New medicines cannot be prescribed until they have been tested to see if they are safe for people to take. This article outlines the processes involved, from laboratory tests to clinical trials.*

Animals benefit from testing involving other animals in the development of veterinary medicines.

New medicines might replace a defective enzyme product, change a biochemical reaction, help substances to move in or out of cells, kill some cells or encourage other cells to grow.

**Right:** The short life and plentiful reproduction of mice allow scientists to monitor impacts on life span and the next generation



**D**iseases happen when things go wrong in the body. Once scientists begin to understand the problem they can search for medicines that will help sufferers. They investigate any potential medicine to show how effective it is and to find out if it is likely to have any harmful or unpleasant side effects.

### Laboratory tests

The effects on cells of a potential new drug are investigated using tissue cultures of human or animal cells. Some tissue cultures use fresh tissue samples, but most come from well-established laboratory cell strains. The cell cultures receive various doses of the test substance and its effects are monitored. If a substance harms abnormal cells, such as cultured cancer cells, or stops viruses infecting cells, it could be useful. At the same time, scientists check that the drug does not affect normal cells.

### Computer modelling

Scientists use what we know about the complex interactions of the human body's biochemistry to make computer models of body systems. New drugs are tested in these systems to see how they affect the natural variations of body chemistry in the human population.

These systems can show unanticipated side effects and interactions between the new substance being tested and other drugs that people might be taking, as

well as with substances such as alcohol and coffee. Undesirable interactions can be 'designed out' by manipulating the structure of the new drug molecule. Computer modelling can even produce detailed information that cannot be generated by existing experiments.

## Testing on animals

Once a new drug's potential for working on diseased tissues has been tested on cells it is time to see if it works in a whole organism. Laboratory cell cultures have a carefully controlled environment with constant supplies of nutrients. This is different from the environment in a human body with its varying levels of nutrients, wastes, hormones and other important biochemicals.

Animal tests tell scientists if a drug affects organs other than the target diseased tissue, what the effective dose and harmful doses are, and if there are likely to be side effects. Data are collected on how the new drug is absorbed, spread round the body, changed or broken down by the body's enzyme systems and excreted, as well as how toxic it is.

Two species of animals, including one which is not a rodent, must be used for such tests. Mice are often used. Some strains of laboratory animals suffer some of the same diseases as humans so some new drugs can be tested for their effects on the actual disease, rather than on healthy animals.

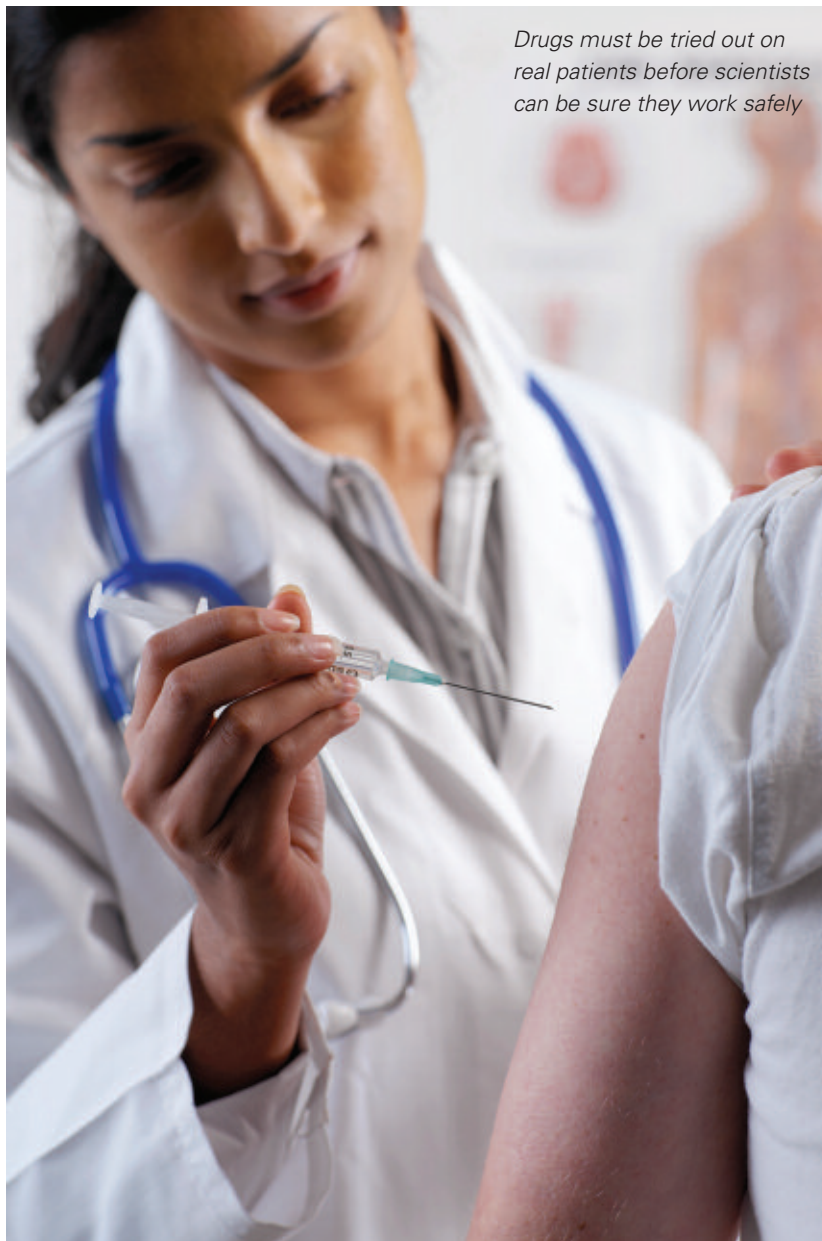
## Clinical trials

Once a drug is shown to be safe and to work in tissue cultures and animals it has to undergo clinical trials on humans. The physiology of other mammals is very similar to our own, but there are important differences. It is only when the drug is in the whole human system that scientists can see its true effects. Some complications are seen for the first time when real people use the drug. Some drugs are given to healthy volunteers first, but they are usually tried on patients.

In more economically developed countries there are ethical guidelines about which patients can be asked to take an experimental drug, and they must agree to being treated with it. The drug's use should be carefully monitored and any side effects recorded. The drug must have a good record in clinical trials if it is to gain a licence for use.

### Box 1 Useful websites

- Log on to [www.abpi-careers.org.uk](http://www.abpi-careers.org.uk) to explore more about the processes involved in developing and testing new medicines, as well as about the scientists involved.
- You can find out about a number of different clinical trials by logging on to [www.bctu.bham.ac.uk](http://www.bctu.bham.ac.uk) and clicking on 'Current trials'.



*Drugs must be tried out on real patients before scientists can be sure they work safely*

Tek Image/SPL

## Blind and double blind trials

Sometimes we really want our experiments to work and unconsciously interpret our results to fit our expectations. If scientists expect a new drug to relieve symptoms they will tend to view what it does in a favourable light.

Data gathered from trials must be assessed objectively so potential new drugs are tested using double blind trials. The doctors who are administering a drug under trial do not know if the medicine they are giving contains the new drug, the usual medicine or a harmless substitute (a placebo). Doctors assessing the patients' symptoms after the course of treatment do not know what medicine the patients received. Who had what medicine is only revealed when the full results are analysed.

**People may report fewer symptoms, or less pain, after they have been taking what they thought was a medicine, even if it did not contain any active ingredients. This is known as the placebo effect.**

- Use the internet to investigate the latest position on the building of the new research laboratory at Oxford University.

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