

# Ethics in science?



Should I?

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# Introduction

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The question scientists should always ask themselves before carrying out an experiment is, I *can* do it, but *should* I do it?

This question becomes more important as our technical scientific capabilities enable us, as a society, to push back the boundaries of the possible. An experiment can be scientifically robust but could still be considered 'bad science' if it fails to adhere to what society considers to be moral or ethical standards. In fact, there are many regulatory bodies and internal committees in the scientific world that are entirely concerned with making judgements about whether science meets suitable ethical standards or not.

Nowadays, we are used to expecting treatments for illnesses to have undergone significant testing in a scientific manner and expect that there should be evidence that something is effective before it is used as a widespread treatment. However, this was not always the case. Centuries ago treatments were often used without any study of their efficacy or with any consideration as to whether they were ethically appropriate – or not.

This OpenLearn course is an adapted extract from the Open University course S111 [\*Questions in science\*](#).

# Learning Outcomes

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After studying this course, you should be able to:

- understand how clinical trials are used today in medicine
- understand the importance of acting ethically in scientific research
- understand why it is important to continue to ask moral questions about scientific research.

# 1 Clinical trials

Clinical trials are the culmination of a significant amount of research undertaken by chemists, pharmacists and biologists in the discovery of potential new drugs. Following the trial statistical analysis of the results is important because noting the change in one person given a specific treatment is not as valid as noting the same change in two or three people and ideally in a much larger group.

The clinical trials that occur today to test new drugs may consist of hundreds of participants. The number of participants or sample size of an experiment is the number of identical observations (replicates) that can be made of the same test. The statistical analysis of the results is more valid if the sample size is larger.

Any drugs trials conducted today follow very careful guidelines. Scientists running trials have legal obligations that are set out in the *Medicines for Human Use (Clinical Trials) Regulations 2004*. One of these is anyone taking part in a trial must have a full understanding of the objectives of the research and any risks and potential inconveniences they may experience when taking part.

## Activity 1 Researching clinical trials

Allow approximately 30 minutes for this activity.

In this activity you will look at the [clinical trials](#) page on the UK's National Health Service (NHS) website and then answer the questions that follow.

Navigate around the website reading information that interests you and taking note especially of the following areas:

- What happens in a clinical trial?
- How are clinical trials regulated and judged to be ethical?
- How many phases are there to a clinical trial and what happens in each phase?

Clinical trials assign people randomly to a treatment group or a control group. What does this mean in practice?

### Answer

- People in the treatment group are given the treatment being assessed.
- People in the control group are given an existing standard treatment, or a placebo if no proven standard treatment exists.

While the treatments are different in the two groups, researchers try to keep as many of the other conditions the same as possible. For example, both groups should have people of a similar age, with a similar proportion of men and women, who are in similar overall health.

In most trials, a computer will be used to randomly decide to which group each patient will be allocated.

Many trials are set up so that nobody knows who has been allocated to receive which treatment, i.e. the trials are 'blind' and this helps to reduce the effects of bias when comparing the outcomes of the treatments.

How are clinical trials regulated and judged to be ethical in the UK?

#### Answer

A government agency called the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) needs to review and authorise them. The MHRA inspects sites where trials take place to make sure they are conducted in line with good clinical practice.

The [Health Research Authority \(HRA\)](#) works to protect and promote the interests of patients and the public in health research. It is responsible for research ethics committees across the UK.

All medical research involving people in the UK, whether in the NHS or the private sector, first has to be approved by an independent research ethics committee. The committee protects the rights and interests of the people who will be in the trial.

For each of the statements below, select the correct clinical trial phase.

Interactive content is not available in this format.

The next section describes what was probably the world's first clinical trial. Undertaken in 1747, it almost certainly would not have been allowed today, although the findings have proved very useful for humans.

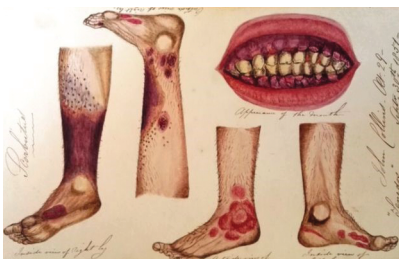
## 1.1 Scurvy: The first clinical trial

Scurvy, a common condition amongst sailors in the 18th century, is rarely seen nowadays, as a result of greater understanding of the causes of this often deadly condition.

Historically, from Greek and Roman times it had been noted that sailors out at sea for periods of more than three months often showed a range of symptoms, including:

- feeling very tired and weak all the time (fatigue)
- a general sense of feeling 'out of sorts'
- pain in the limbs, particularly the legs
- the appearance of small red-blue spots on their skin.

The condition was reported to cause 'funguous [sic] flesh... putrid gums and... dreadful terrors' (according to *Lind's Treatise on Scurvy*, 1753), all now known to be symptoms of scurvy.



**Figure 1** Historical symptoms of scurvy – 'funguous [sic] flesh and putrid gums' – courtesy of the Institute of Naval Medicine Historic Collections.

Watch Video 1 (*What the Industrial Revolution did for us*, 2003) to discover more about scurvy.

Video content is not available in this format.

**Video 1** *What the Industrial Revolution did for us*. Presenter Dan Cruickshank tells the story of the first clinical trial, proving that oranges and lemons could save the lives of sailors by preventing scurvy. (2:48 min)



- What are the symptoms of scurvy?
- Scurvy was a debilitating disease of sailors that resulted in loose teeth, haemorrhaging gums, bruises on the skin and eventually heart failure and death.
- In Lind's experiment on the treatment of scurvy six pairs of men were each given one of the treatments. Why do you think there were two men for each treatment?
- If something happened to one of the men (such as sudden death), the other would still be observable in the experiment. And if both survived, Lind was ensuring that he had one replicate result for each test.

## 1.2 Scurvy trial: Ethical critical review

From an experimental design perspective, Lind did his best to ensure that his clinical trial was sound by ensuring that the subjects were physically similar as far as possible and also appeared to be affected by scurvy to a similar level. He also ensured that, with the exception of the experimental treatment, the sailors had the same diet and were kept in the same area of the ship. In addition, in the 1700s, all sailors would have been male so sex would not affect the results. With the knowledge available to him, Lind did a good job of attempting to choose similar subjects which means he controlled as many variables that may have affected the results as he could.

However, the sailors would have varied from each other in terms of their age, height, weight and level of scurvy symptoms and any of these factors could have had an impact on the result of the experiment. We can now also identify the fact that the sailors would have been genetically different, and it is not possible to rule out an individual's genetic make-up as a factor influencing results. In addition, these sailors may have had other conditions or ailments that may have made them more vulnerable to sickness.

Nowadays Lind's clinical trial would be considered unethical. One reason is that the participants were not volunteers and they had no choice but to be involved in the



experiment. Another reason is that the outcome of the experiment in terms of the sailors' health was unknown, which is unethical because it could have resulted in the sailors becoming even sicker or dying. In fact, some of the treatments may have been harmful rather than simply ineffective. For example, nowadays it would not be acceptable to give experimental subjects sulfuric acid on an empty stomach!

It is also hard to say how informed the sailors were of the risks of the experiment. In modern scientific studies involving humans, informed consent must always be acquired, and the participants can withdraw from the trial at any time. These rules are governed by ethics committees and ethical guidelines.

You will be relieved to know that the experiment conducted by James Lind would not be allowed today!

## 2 Research integrity

Below is a case study on Edward Jenner, who conducted an early medical trial on a living human subject. The results of his experiment are an example of a great scientific advance, but today the ethics would be very questionable.

### Edward Jenner - a case study

Edward Jenner (1749–1823) was a doctor and in 1796 he carried out an experiment which led to him becoming known as ‘the father of immunology’. The experiment involved inoculating an eight-year-old boy, James Phipps, with pus from a cowpox pustule taken from an infected milkmaid. When James recovered he was then later infected with smallpox pus in the same manner.



**Figure 2** Edward Jenner inoculating a child.

Jenner was testing a hypothesis that followed his observation of local folklore, which said that milkmaids who suffered from cowpox did not suffer from smallpox. Smallpox infection was a big killer, especially in children, in the 1790s, but cowpox was a mild disease. Jenner's hypothesis was that people who suffered from cowpox would not then suffer from smallpox. This hypothesis was confirmed (albeit in a sample of one).

There is a great deal of difference between unknowingly and knowingly practising what could be termed ‘bad science’. Under today's strict legislation James Lind and Edward Jenner would not have been able to conduct their experiments.

In 2006 the UK Research Integrity Office (UKRIO) was established. According to its website, UKRIO is:

an organisation that offers support to the public, researchers and organisations to further good practice in academic, scientific and medical research. The UKRIO promotes integrity and high ethical standards in research, as well as robust and fair methods to address poor practice and misconduct.

In the following activity you will learn more about the role of UKRIO.

## Activity 2 UK Research Integrity Office

You should allow about 30 minutes for this activity.

While the UKRIO is relevant to the UK, there are similar organisations in other countries of the world. Spend some time researching the website of the [UKRIO](#). While you are researching think about finding the answers to the following questions:

What sort of organisation is UKRIO?

### Answer

UKRIO is a charity and an 'advisory' body, not a regulatory body.

What are the aims of the UKRIO?

### Answer

The aims of the UKRIO are to:

- promote the good governance, management and conduct of academic, scientific and medical research
- share good practice on how to address poor practice, misconduct and unethical behaviour
- give confidential, independent and expert advice on specific research projects, cases, problems and issues.

What are the principles of the UKRIO?

### Answer

The principles of the UKRIO are: excellence, honesty, integrity, cooperation, accountability, training and skills, safety.

What should researchers do to ensure they follow good practice?

### Answer

Researchers should:

- recognise their responsibility to conduct research of high ethical standards
- be aware of their organisation's policies and procedures on good practice in research
- make sure that their research complies with these policies and procedures, and seek guidance from their organisation when necessary
- work with their organisation to ensure that they have the necessary training, resources and support to carry out their research; and
- suggest to their organisation how guidance on good practice in research might be developed or revised.

Poor practice, fraud and other forms of misconduct can cause significant harm to the public perception and, indeed, the reputation of scientific research.

Scientific research is undertaken through funding from charities, taxes and commercial companies. Any breach of trust with the public due to misconduct and poor practice can cause considerable financial and reputational damage to research institutions and jeopardise further funding opportunities. Most importantly, participants, patients and the public can be put at risk or even caused actual harm.

In the UK in 2006 there was a clinical trial that went seriously wrong. The clinical trial became known in the popular press as the ‘elephant man drug trial’ and it was the first phase of the trial of the drug known as TGN1412 in humans. It was hoped that the drug might be used in the treatment of cancer and rheumatoid arthritis. The trial involved eight healthy men aged 19–34 years. Six men received TGN1412 and two men received a placebo ( a placebo is a substance with no therapeutic effect).

- Why do you think it is important to use a placebo in a clinical trial?
- The placebo acts as the ‘control’ in the experiment. This means that any differences noted between people given a drug and people given a placebo in a clinical trial can be attributed to the drug and not to the way the drug was administered.

The people involved in the clinical trial were not aware of whether they were given the placebo or the test drug. The six men who received TGN1412 all complained of severe pain within two hours of being infused with the drug and all were in intensive care within 12 hours of the infusion. One volunteer was described as having a ‘ballooned head’, hence the ‘elephant man drug trial’ label; another volunteer lost his fingers and toes.

It is important to view the ‘elephant man drug trial’ in context. It was one drug trial out of thousands conducted every year and fortunately none of the volunteers died. The fact that the trial received such broad press coverage at the time was precisely because it was unusual and horrific for those involved. It is important that scientific research is open to scrutiny as this promotes good practice because of the wider consequences.

It is vital to promote integrity in our scientific research. The experiments undertaken by Lind and Jenner would be considered unethical by today’s standards. But they did undertake their experiments with the best intentions; that is, to provide a cure for scurvy and prevention for smallpox.

However, there are other scientists that do act unethically either for their own glory or for money or for some other reason. These scientists are few and far between, but it is important that they are exposed for bringing science into disrepute.

## 2.1 Unethical scientists

Unfortunately there are examples of ‘bad scientists’ from every discipline in science, although the examples are few and far between. The fact that scientists publish their results in highly respected journals such as *Science* and *Nature* which are peer reviewed must reduce the number of spurious and fraudulent papers that are published. However, there are still a few occasional cases of fraudulent papers that get published even in these journals.

In Activity 3 you will be looking at fraudulent scientists from the disciplines of physics, chemistry and biology. You will use the internet to find out more information about three ‘bad’ scientists.

### Activity 3 ‘Bad scientists’

You should allow about 1 hour for this activity.

Use your internet searching techniques to find out more about the following scientists. Summarise your findings in under 100 words for each scientist, saying who they were and stating why their work was fraudulent. When you use information from a website, always remember to ask yourself – is this a reliable source of information?

- Jan Hendrik Schön
- Haruko Obokata
- Pattium Chiranjeevi

#### Answer

For this example, Wikipedia was used as the primary research source for Schön and Obokata, but be sure to check the salient facts with hyperlinks to other authoritative sources. The primary source for Chiranjeevi was an article on [www.chemistry-world.com](http://www.chemistry-world.com).

- Jan Hendrik Schön was a physicist whose research was in the area of semiconductors (crystalline or amorphous solids with distinct electrical characteristics). He had a number of papers published in notable journals including *Science* in 2000 and 2001, which have since been retracted. Schön made up his results.
- Haruko Obokata (小保方 晴子), born in 1983, was a stem-cell biologist at the Riken Center for Developmental Biology in Japan. She claimed to have developed a radical and comparatively easy way to make stem cells by subjecting ordinary cells to certain types of stress, such as submersion in a weak acid or physical trauma. The proposed method was known as 'stimulus-triggered acquisition of pluripotency' (STAP) and would create cells that could be grown into tissue for use anywhere in the body. Obokata made up her results.
- Pattium Chiranjeevi, a chemistry professor in India, authored 70 papers published between 2004 and 2007 in highly reputed international journals. He was found guilty of plagiarising other scientists work in 2008.

Hopefully the last activity hasn't left you feeling too negative about scientists! The fact that these cases of misconduct make the national news is reassuring as it emphasises that malpractice in science in whatever form is wrong. The fact that these names are well known throughout the scientific community shows how their fraudulent practices are frowned upon and it is also notable that there were significant consequences for these scientists. Scientists are human and have the same failings as the rest of the human population, falling prey to greed and wanting fame.

Scientists, like everybody, can make genuine mistakes. The important thing is that scientists admit to them. Daniel Bolnick, an ecologist, described the 'sinking feeling in his gut' when he realised he had made an error in a paper published in *Evolutionary Ecology Research* in 2009. He did the right thing; he wrote to the journal and asked for a retraction. You can read an interview with Daniel Bolnick in [Retraction Watch](#) where the error is described, and his blog post where he explains clearly how the error occurred.

## 2.2 Moral dilemmas in science

There are numerous examples in current or historical science that involve serious ethical considerations. A few are listed below. For each example, list some of the factors that should be taken into consideration. (Note: your answers are likely to differ from mine.)

- Should we alter the genome of a human embryo?
- While altering the genome of a human embryo could provide medical benefits, the question remains as to whether we should be doing this at all and, if so, whether this applies to all circumstances. For example, if we are able to edit the genome to prevent disease, should we also be able to edit the genome to choose 'desirable' traits?
- Should we land machines, or humans, on planets, comets or other extraterrestrial bodies in order to study them?
- Whenever we introduce something to an environment, we have the potential to alter that environment. But should this possibility prevent us doing this research?
- During the Second World War, the Nazi concentration camps were the site of a large number of dreadful experimental studies on prisoners. Should we use any of these data if they have the potential to save lives today, even though we condemn the methods used to collect it?
- The feelings of the relatives of the people in the prisoner of war camps should be considered. Who 'owns' the data? What benefit could analysing the data give? Should any data that arises from such an appalling source just be destroyed?
- Can we justify the amount of expenditure on all scientific research?
- How much is spent on scientific research? How much is spent on which areas of scientific research? Should medical research receive more funding than space research, for instance?

None of the questions asked have a 'right' or a 'wrong' answer; they are a matter of opinion. Think about what you would consider when making up your own mind about each of the questions above.

A moral dilemma arises in the case of Fritz Haber (1868 –1934). Haber was a German chemist who received the Nobel prize in chemistry in 1918 for the invention of the Haber–Bosch process. This method makes ammonia from nitrogen and hydrogen gases and is important in the production of nitrogen fertilisers. He also devoted much of his work in the early part of the 20th century to developing weaponised gaseous chemicals and he was an enthusiastic proponent for their use in World War I, for which he has been called the 'father of chemical warfare'. It is interesting to consider whether the benefits of the Haber–Bosch process outweigh the moral issues inherent in his position on the use of chemicals in conflict.

## Conclusion

Hopefully you now have a taste for how complex the moral and ethical issues surrounding scientific experimentation can be.

The ethics of what is 'good' and what is 'bad' science are challenging to consider and are never simple to disentangle. They are also highly contextualised by the society of the time – there are things which are viewed as unacceptable now either because of changing societal views or because, with the benefit of hindsight, we have a clearer understanding of their future impact.

The key concepts and principles you have studied in this part are:

- how clinical trials are used today in medicine
  - Clinical trials use a control group and a treatment group.
- the importance of acting ethically in scientific research
  - The UK Research and Integrity Office advises on good practice on scientific research.
- why it is important to continue to ask moral questions about scientific research.



This course is part of a suite of introductory science courses on OpenLearn.

The content of these courses comes from the Open University course S111 [Questions in science](#). Take a look at the other OpenLearn courses that are part of this set [here](#).

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## Acknowledgements

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