

A code of conduct for scientists

Introduction

Should scientists be responsible for the effects of their research on society? Do they have a responsibility to other scientists? What ethical codes should scientists adhere to? In this activity students read three case studies and answer questions about them. They are then asked to look at a newly established code of conduct for scientists and relate it to the case studies.

The activity

Information in case studies B and C is taken from longer press reports. Links to these reports are given and you may wish to use the originals. The questions will probably be best answered in small group discussion. If time allows have a final short class discussion on the question “Will the universal ethical code for scientists prevent fraud and other unethical behaviour? “

Suggested Answers

Case Study A

1. Healthy volunteers have nothing medically to gain from undergoing a drugs trial. It could be argued that it is more ethically acceptable to use volunteers who are suffering from the condition targeted by the drug, as there is at least a possibility that they will benefit from the treatment. However, it can also be argued that ‘real’ patients should be reserved for Phase 2 trials, as they are difficult to recruit in suitable numbers. Phase 1 trials are testing for safety and so healthy volunteers are suitable. Cost-benefit analysis favours using healthy volunteers: the gain for sick people in developing a new drug outweighs the (usually) small risk of an adverse reaction in a Phase 1 trial.

2a) This sum is larger than usual and gives rise to the suspicion that there was knowledge about a higher than usual risk from the drug at the outset.

b) Giving a fee for time taken avoids the contentious issue of paying a larger fee for taking a greater risk. Young people or poor people may be tempted to take a risk for personal gain which is not in their best interests.

3. It is advisable to wait a reasonable length of time after treating the first volunteer in case there is a severe reaction. The agreed protocol for the trial stipulated a period of 2 hours in which to give the treatments.

How Science Works

Eb Findings reported by an individual scientist or research group, and their interpretations of these, are carefully checked by the scientific community before they are accepted as reliable scientific knowledge. This process of ‘peer review’ is essential both for detecting invalid claims and adding weight to valid ones.

Ec Scientists publish their work in technical journals, in conference papers and on the internet. This enables other scientists to see and comment on the data collected, the methods used, and the interpretations made.

Ef In situations where scientific explanations are contested and different conclusions can legitimately be drawn from the available data, the personal background and interests of scientists (e.g. their education, past experience, previous areas of work, political and/or religious views, the interests of organisations they work for) may influence their judgments.

Eg The desire to be first to a new discovery or breakthrough is a powerful motivation for scientists, and can lead to competition
Fd In assessing how much trust to place in a reported scientific claim, it is important to assess the extent to which it has been subjected to peer review. It may also be reasonable to take account of the seniority, reputation, and place of work of the principal scientists involved.

Hi Scientists have an individual responsibility to ensure that their practice is ethical. This may be detailed in a professional ethical code. Such codes may also form the basis of regulatory decision by ethics committees. National or international regulations that apply to scientific activity may have an ethical basis.

4. The drug targets human cells so it makes sense to test the drug on other primates first. However, extra caution should have been used because the drug would be expected to be much more potent in humans than monkeys.

Case Study B

1a) Hwang was looking for respect and scientific prestige. He had excellent facilities and human resources, so he had a good opportunity to crack a problem at which others had failed and which had great potential for medical advances. He put himself in a position where there were great expectations of him and he could not face the possibility of failure. He presented his results at international conferences, showing video clips of the procedures he used.

b) He was given a lot of independence and freedom in his work because he was highly regarded by his colleagues and by his country. Hwang's colleagues may have known about the fraud but were afraid to speak out.

2a) Peer review means that papers submitted to a journal for publication are sent to anonymous referees who look carefully at the paper to check that the conclusions are valid and that the correct statistical tests have been applied. They may also examine ethical issues, such as the use of animals in experiments. The reviewers are scientists who are familiar with the field of study but have no links with the authors of the paper.

b) When results are highly original or surprising, it is now thought advisable for journals to request examination of the primary data.

3. The public's trust in scientists is damaged by such cases, and leads to a suspicion that scientists generally lack integrity.

Case Study C

1.a) Funding can lead to a conflict of interests, whereby pressure is put on the scientist to find that the drugs produced by his/her sponsor are effective. It could lead the scientist to falsify data or misinterpret data. It might also encourage a scientist to over-diagnose the condition which the drug treats.

b) It can be argued that drugs trials should only be funded by neutral agencies such as state funding. However, this restriction would greatly reduce the amount of research into new treatments. There may need to be a compromise between ethics and practicality.

A universal ethical code for Scientists

Case study A

Rigour - Failure may have been lack of care in not recognising the risk of an adverse effect in humans.
Respect – injecting all the volunteers at about the same time showed failure to minimise any adverse effect.

Case study B

Rigour – Hwang did not take steps to prevent corrupt practices in putting pressure on his assistants to donate eggs. Fraudulent results is professional misconduct.
Responsibility – he knowingly misled others about scientific matters.

Case study C

Rigour – Biederman did not declare conflicts of interests.
Responsibility – it is likely that he has exaggerated the beneficial outcomes of some of his trials.

January 2009



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Introduction

Should scientists be responsible for the effects of their research on society? Do they have a responsibility to other scientists? What ethical codes should scientists adhere to? In this activity you will read three case studies where the work of scientists raises issues about ethics and codes of practice, and discuss questions about them. Lastly you are asked to look at a newly established code of conduct for scientists and relate it to the case studies.

Case Study A - A trial that went wrong

In 2006 healthy male volunteers were recruited by a drug trials company to test a drug called TGN1412 in a double blind randomised trial. TGN1412 targets the T-cells of the immune system; it was being developed to treat diseases such as multiple sclerosis and rheumatoid arthritis.

Good clinical practice requires volunteers to be paid for time taken by a trial rather than for the degree of risk, but the payments for this trial were higher than usual. The volunteers were paid a fee of £2000.

All volunteers were inoculated within about 20 minutes of each other. The drug was administered at 1/500 of the maximum concentration tested in monkeys for safety. Monkeys developed swollen lymph glands but were otherwise not affected. The antibody in the drug targets human T-cells.

The six volunteers who received the real drug (rather than a placebo) became ill soon after being injected with the drug, suffered multiple organ dysfunction and were taken into intensive care within hours of receiving the drug. All suffered symptoms of a severe allergic reaction, and were in hospital for a month or more. It is thought that they may have sustained permanent damage to their immune systems.

Questions to discuss

What went wrong?

Comment on the following with reference to good clinical practice or ethical principles:

1. Using healthy volunteers
2. a) Paying a £2000 fee to young volunteers.
b) Paying a fee for time taken rather than for the degree of risk.
3. Injecting volunteers within 20 minutes of each other.
4. Testing a drug on monkeys when it specifically targets human cells.

Case Study B - The disgrace of Hwang Woo-suk

Human stem cells hold the promise of treatments for many diseases and scientists had been trying and failing for years to create stem cell lines from cloned human embryos. Then in 2004 Hwang Woo-suk claimed to have created 30 cloned embryos and extracted stem cells from them, and in May 2005 he and his team said that they had made eleven different stem cell lines from human skin cells. They published their results in the prestigious journal *Science*. Hwang went from being a respected and well funded scientist to a celebrity, in his home, South Korea, and around the world. He had a Korean state title "Supreme Scientist".

Then rumours started, had he obtained the necessary human eggs from his own research assistants, were some of the images in his papers false, were there really eleven separate stem cell lines or only two? One of his colleagues claimed the research was faked. When, in December 2005, Seoul University began investigations they discovered that almost nothing was as it had seemed. Far more human eggs had been used than claimed in the published papers, the cell lines were not from cloned human embryos, some of the generous research funds had been used for personal luxuries. The journal *Science* retracted the papers and at his trial Hwang finally admitted fraud.

What does this mean for stem cell research? Dr Stephen Minger is a stem cell researcher at King's College London. He gave an interview to the BBC in which he said, "In terms of the science, it has really taken us back to square one. Nobody has got close to doing what Dr Hwang claimed to have done. Hwang seemed to have all the resources and an endless supply of human eggs to use. But here and elsewhere people cannot push this field forward because there is a profound shortage of eggs - and this is a major problem."

How does this affect other research? An eminent geneticist told the BBC "Any story of scientific fraud causes concern and panic amongst scientists. People start asking questions like: 'How do I know members of my lab aren't faking data?' or: 'Is my boss's interpretation of my data right?'"

Another scientist suggested that Hwang had benefited from a supportive and mostly unregulated political and legal environment and that he was subjected to many pressures, but few constraints.

What should journals do? The editor of *Science* wrote: "The environment for science now presents increased incentives for the production of work that is intentionally misleading or distorted by self-interest." It seems that peer review - the process by which journals get independent experts in the field to check the quality of a paper to deem it worthy or not for publication - may no longer be enough. High risk" papers - research that is of significant public interest, has unexpected or counterintuitive results - submitted to *Science* now faced extra editorial scrutiny, he explained.

An editor of *Nature* told the BBC: "This has made us much, much more wary," The journal would pass a more critical eye if a paper came to it purporting to have done what Dr Hwang claimed he had done", she said. "It's better to be safe than sorry - the science has to be absolutely watertight." The journal might ask to see the primary data and to be given more detailed information on each author's role in the work.

Source: BBC news <http://news.bbc.co.uk/1/hi/sci/tech/6280491.stm>

Questions

1. a) Suggest reasons why Hwang was tempted to fabricate his results about cloning human stem cells.
b) Suggest what circumstances could have allowed Hwang to get away with his dishonesty for so long.
2. a) What is meant by 'peer review' of a scientific paper?
b) Explain why peer review is not now thought to be adequate support for the publication of some scientific papers.
3. Suggest how this case has affected the public's perception of scientists.

Case Study C - Researchers Fail to Reveal Full Drug Pay

Dr Joseph Biederman is a world-renowned child psychiatrist who works at Harvard University. He is an expert on ADHD and has also promoted the diagnosis of bipolar disorder in children and the use of anti-psychotic drugs to treat these children. Many child psychiatrists have tremendous respect for his work and believe that it has helped some severely ill children. But others claim that the research trials on which the ideas are based used only small samples and may be subject to bias.

Much of his research and that of his colleagues is funded by drug companies, including Johnson & Johnson, the manufacturer of one of these ant psychotic drugs. However not all this research funding was declared to the University. When investigations began these scientists belatedly admitted that they had received sums ranging from \$3500 to \$1.6million from drug companies. Further investigations showed that even these sums may be less than the true value. In some cases the drug companies stated that they had paid higher amounts than those declared by the researchers.

Research is very expensive and most doctors receive funding from drug companies to allow them to do the work they would otherwise be unable to do. However disclosure of these sources should be made both to the university and to the trial subjects to allow potential conflicts of interest to be policed. Dr Biederman is being investigated by the university.

Source: <http://www.nytimes.com/2008/06/08/us/08conflict.html>

Questions

The scientists are criticised for not revealing funding from drugs companies for their research.

1. Explain the reasons why the scientists should have revealed their funding sources.
2. Comment on whether it is ethically acceptable for scientists to be funded by drugs companies for research into drug into treatments, even if they do reveal their funding sources.

Do Scientists need a code of ethics?

Professor Sir David King, formerly the government's Chief Scientific Advisor, has recently published seven principles to provide an ethical code for scientists. It is aimed at building trust between science and society.

1. Give at least one example from each of the three case studies above of a transgression of one of principles listed below.
2. What would you say in a discussion aimed at answering the question "Will the universal ethical code for scientists prevent fraud and other unethical behaviour? "

Rigour, respect and responsibility: A universal ethical code for scientists

Rigour, honesty and integrity

- Act with skill and care in all scientific work. Maintain up to date skills and assist their development in others.
- Take steps to prevent corrupt practices and professional misconduct. Declare conflicts of interest.
- Be alert to the ways in which research derives from and affects the work of other people, and respect the rights and reputations of others.

Respect for life, the law and the public good

- Ensure that your work is lawful and justified.
- Minimise and justify any adverse effect your work may have on people, animals and the natural environment.

Responsible communication: listening and informing

- Seek to discuss the issues that science raises for society. Listen to the aspirations and concerns of others.
- Do not knowingly mislead, or allow others to be misled, about scientific matters. Present and review scientific evidence, theory or interpretation honestly and accurately.

Source: http://www.dius.gov.uk/policy/science_society/code.html