Appendix 3

Defining ethics and making ethical decisions

What is ethics?

First, we can agree on what ethics is *not*. Table A3.1 lists forces in our society that are all concerned with **right and wrong** in various ways. We may be influenced by one or more, but these concepts are not, themselves, ethics.

Table A3.1 Defining ethics by recognizing what it is not

The Law	Religion	Cultural norms	Science	Our feelings/ conscience
Our laws are made by governments and may not be ethically-based. (They may be based on views held by a powerful clique.)	In our society, there are followers of different religions, and of none, yet ethics apply to us all.	Many are little more than 'fashions' that seem acceptable at the time, yet are held uncritically.	While science seeks to give understanding of the origins of our world, it may not suggest how we should act.	These are likely to be the products of our early environment, general outlook, our individual experience, and our temperament.
Can you think of examples to do with the law, religions, cultural norms, science or conscience which you feel are not ethical? This is perhaps most difficult in the case of 'our feelings'.				

Next, we identify the criteria that are relevant in making ethical judgments (Table A3.2).

Table A3.2 Ethical criteria to apply in decision making

Factors we should use in determining an ethical position on an issue	
Rights – it is our duty to ensure these	Human rights: • The United Nations Universal Declaration of Human Rights: 'All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood' • The European Convention on Human Rights, which includes security, liberty, political, due process, welfare/economic and group rights • Countries with a Bill of Rights written into their Constitution, for example in the USA: '*We hold these truths to be self-evident, …*'
Justice – a principle to guide actions	All should be treated equally – the idea of fairness in our actions towards each individual is essential.
Utilitarianism – benefits should be greater than the 'costs'	The principle of the greatest good for the greatest number, and with actions that generate minimal harm to others' interests. In effect, this involves a cost–benefit analysis.
Common good – a core conditions (the welfare of all)	In a working community, all actions should support the common interest.
Virtue – the need to live a 'good life'	Ethical actions reflect values like truth, honesty, courage, compassion, generosity, tolerance, integrity, fairness, self-control and prudence.
Other criteria?	*Can you suggest any other criteria and convince your peers of their importance?*

Making ethical decisions

Agreement on the criteria (such as given in Table A3.2) is a first step. Then, we need to formulate a **reasoned explanation** for an ethical approach to an issue that all or most can accept. This approach should come from discussion and argument.

- When preparing a personal statement of view, you might select two or more of the listed ethical standards and show how each guides you to your opinion. So, for example, you might identify all parties directly involved in the issue and reason why the 'rights' of each must be respected. Similarly, you might calculate the 'costs' and the 'benefits' for a good society of the position you advocate.

- Next, individuals need to state their views simply. Peers should listen and prepare questions which develop their understanding and which probe the case being made. *All* distinctive views and opinions on the issue under discussion need this same exposure.
- Finally, a common view is needed. Remember, this may not be a majority view – established by means of a vote, for example. Sometimes a minority view is the most ethical response, and this is adopted.

Ethical decision-making in context

We can illustrate this process by taking a likely issue – such as 'animal rights'.

You may have learnt about the conditions under which a dog was held in Pavlov's experiments on the control of digestion (page 29 Chapter 12).

Today, the involvement of laboratory animals in research is extensive. It is estimated that a total of 3 million animals are used annually in the UK; in the USA the figure is possibly in excess of 20 million; globally the estimate is that 50 million animals are used every year. About 90% of the animals are rodents.

The idea of carrying out an experiment that is expected to cause pain to an animal is unacceptable to most people. This revulsion has led to the introduction of laws that attempt to eliminate any unnecessary suffering. Even so, some people believe that no experimentation on animals can ever be justified.

Issue for discussion

Are there circumstances in which we should accept the need for experiments on animals, accepting the possibility that these may cause stressful or unpleasant conditions for them at times?

Table A3.3 considers the ethical issues relating to the use of animals in medical research.

Table A3.3 Two positions on animal experiments

In favour of animal experiments – *experimenting with animals is acceptable if:*	**Against animal experiments – *experimenting with animals is always unacceptable because:***
suffering is minimized in all experiments	it causes suffering to animals
human benefits are gained that cannot be gained by other means	benefits to humans are unproven or could be obtained by a different approach

Situations to consider by group discussion

Challenge 1

'The needs and rights of the non-human animal world should not stand in the way of the advantages to be gained from their selective, supervised use in medical research in certain circumstances.'

Tabulate the essential contrasting points you feel that an 'animal rights' supporter and an 'animal welfare' supporter would make.

Challenge 2

Imagine a (highly plausible) situation in which approval is needed for the use of animals (say rodents and primates) in a programme to test the safety and efficacy of a particular experimental vaccine against malaria. The activities of the malaria parasite (*Plasmodium*) kill more children around the world than any other disease.

Could you approve this? Why/why not?

Take some time over resolving your own response to this challenge. In view of the extent of the harm caused by malaria, this challenge may become a practical issue in your lifetime.

Challenge 3

Effective vaccines are needed to combat outbreaks of the highly contagious Ebola virus. Normally, when new drugs become available they are subjected to rigorous, time-consuming safety tests and checks (see 'The development of modern drug-testing routines', page 3).

In attempting to combat a disease, and the very high mortality that results, in a community under threat, is there a case for a drug to be released to vulnerable populations before its absolute safety and efficacy has been established?

Ethical issues raised in the IB Diploma Biology course

Ethical issues are raised in these parts of the book.

Page	Issue
15	Use of stem cells in research
120	Use of non-vertebrate animals in a respirometer
452	Jenner's vaccine testing, using both himself and a child

The development of modern drug-testing routines

Today in the UK, new drugs and medicines have to be approved by a government agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), following a rigorous regime of critical trials that also requires the approval of the MRHA. Manufacturers and distributors are licensed by the MRHA, too. The financial cost of a product does not enter into the Agency's decision-making process; there are other official bodies that assist our National Health Service (NHS) to decide on the cost-effectiveness or otherwise of a drug or medicine. You can learn more about the work of the MRHA by visiting their website: www.mhra.gov.uk/

The clinical trials procedures are summarised in Table A3.4 below. These trials extend over a prolonged period; it takes very many years to develop a new drug.

Table A3.4 Stages of the drug-testing regime

Stage	*Procedure*
1 Pre-clinical stage of drug development	Involves extensive laboratory tests to ensure safety when delivered to humans, covering the composition of the drug, its manufacture, and how it will be safely delivered. The effect of the drug on cells and tissues (*in vitro* studies), and trials with animals – referred to as 'animal models' – are studied. Toxicology studies are required to identify possible risks to humans. Then formulation of the drug in a form it can be administered, e.g. as a nasal spray or time-release capsule, is carried out.
If the drug now receives approval for the next stages, these will all involve humans, i.e. *in vivo* studies. Successful outcomes are needed at each of the following stages for the trial is to be allowed to continue.	
2 Phase I Clinical studies	A number of healthy volunteers, typically 20–100 people, receive the drug for a limited period, after being fully briefed on its intended effects. Investigations monitor the way the drug is metabolised in the body and what effects it has. This phase lasts for less than one year.
3 Phase II Clinical studies	A larger group of volunteer patients *with the condition the drug is designed to treat* are selected, normally involving a group of several hundred. Both safety and effectiveness of the drug are the focus of these trials, which require from 6 months to 3 years. The patients are typically divided into two or three randomized groups, one receiving the drug and one receiving a placebo (and possibly one group receiving the current standard treatment). These trials are 'double blind' – neither patients or the administrators of the treatments know which is receiving the placebo or the drug.
4 Phase III Clinical studies	Finally, expanded versions of Phase II trials are now mounted, randomized and double blind again. Many hundreds of patients with the condition are involved, and the trials last for up to 4 years.
If the outcomes of the above have all been satisfactory, the drug may be approved for a marketing licence.	
Post-approval studies	Issues like new side-effects that have emerged, and the response of different age groups to the drug, may need to be reviewed.

The ethics of the human 'control' group in drug trials – a historical case

In 1984 an organic chemist at the drug firm Burroughs Wellcome in the USA investigated the compound AZT (azidothymidine) as an antiviral agent against retroviruses (HIV; the virus causing AIDS is a retrovirus). The compound was tested in cats and mice, and was discovered to be successful. After this, the first human beings were injected with AZT in July 1985. Of the 17 AIDS patients who were treated, 15 showed an improvement in health and they put on weight.

Then came further trials (Phase III, in effect), but these proved ethically controversial because the patients in the control group (who received a placebo*) showed no improvements and many died quite quickly – rather as to be expected from their medical condition, as it was treated at the time. Meanwhile, the health of those treated with AZT improved significantly.

Can you see how this trial was ethically challenging for the medical staff concerned?

However, the drug was finally patented by Burroughs Wellcome in 1985, and has gone on to be used widely, with significant benefits for patients.

*Note: today, a placebo is defined as a medicine or treatment prescribed for psychological benefit to the patient, rather than for any physiological effects.