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Revision

Trialling a malaria vaccine

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Although the aim of the *Prospects* column in BIOLOGICAL SCIENCES REVIEW is to provide information about careers linked to biological sciences, the April 2013 issue includes some relevant discussion of the clinical trials that must be completed before a drug can be licensed for use. It progresses to consider some of the ethical issues that form an important part of How Science Works. This resource comprises two worksheets:

- Making ORS safer
- Trialling a malaria vaccine

They link to the *Prospects* column and explore both the protocols involved and the underlying ethical issues. Oral rehydration solutions and malaria occur on some specifications but not on all. Knowledge of these topics, however, is not necessary in order to attempt the worksheets.

The teacher notes that accompany the student worksheets have been set out in the same way in both instances:

- **Objectives:** these relate primarily to the different aspects of How Science Works that underpin the present A-level science specifications.
- **Overview:** as the title suggests, this gives a brief sketch of the underlying biology.
- **Further information:** should you wish to look at the original source material, the reference is here. In both cases this material may be downloaded at no charge.
- **Suggested marking guidelines:** these guidelines give an indication of what might be expected by way of answers. They are intended as a basis for discussion.

Trialling a malaria vaccine

Objectives

This exercise is designed to emphasise the following aspects of How Science Works:

- Use knowledge and understanding to pose scientific questions, define scientific problems, present scientific arguments and scientific ideas.
- Use appropriate methodology to answer scientific questions and solve scientific problems.
- Carry out experimental and investigative activities, including appropriate risk management, in a range of contexts.
- Evaluate methodology, evidence and data, and resolve conflicting evidence.
- Consider applications and implications of science and appreciate their associated benefits and risks.
- Consider ethical issues in the treatment of humans, other organisms and the environment.
- Appreciate the role of the scientific community in validating new knowledge and ensuring integrity.
- Appreciate the ways in which society uses science to inform decision-making.

It links to the following topic, found in most specifications:

- Immunity and vaccination

Overview

Although malaria is only on some biology specifications, students who study the topic of vaccination should be able to apply the principles underlying How Science Works and

- evaluate methodology, evidence and data relating to the use of vaccines
- discuss ethical issues associated with the use of vaccines
- explain the role of the scientific community in validating new knowledge about vaccines, thus ensuring integrity

This exercise looks at some of the preliminary results from a phase 3 trial of a new malaria vaccine carried out on African children. Students do not need to know anything about malaria other than that it is an infectious and potentially fatal disease, resulting in the deaths of many children in Africa.

Further information

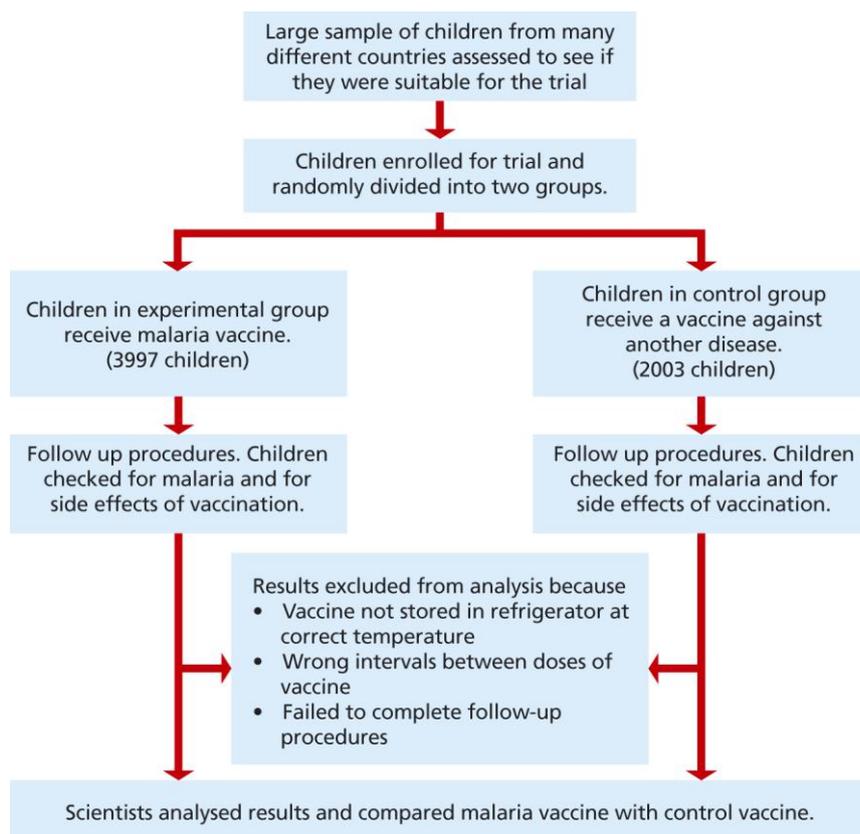
This exercise has been developed from information in: RTS,S Clinical Trials Partnership (2011) 'First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children', *The New England Journal of Medicine* Vol. 365 No. 20.

This paper is available from the internet.

Worksheet: trialling a malaria vaccine

Malaria is a severe disease caused by a parasite that is spread through bites of infected mosquitoes. It accounts for approximately 22% of all childhood deaths in Africa.

Recently a new malaria vaccine has been developed. This vaccine is now being trialled in different countries in Africa. The flow chart shows the protocol for this trial.



1 This malaria vaccine is based on some amino acid sequences that are found on the surface of malaria parasites. Use this information to explain how the vaccine can help to protect people against malaria. (5 marks)

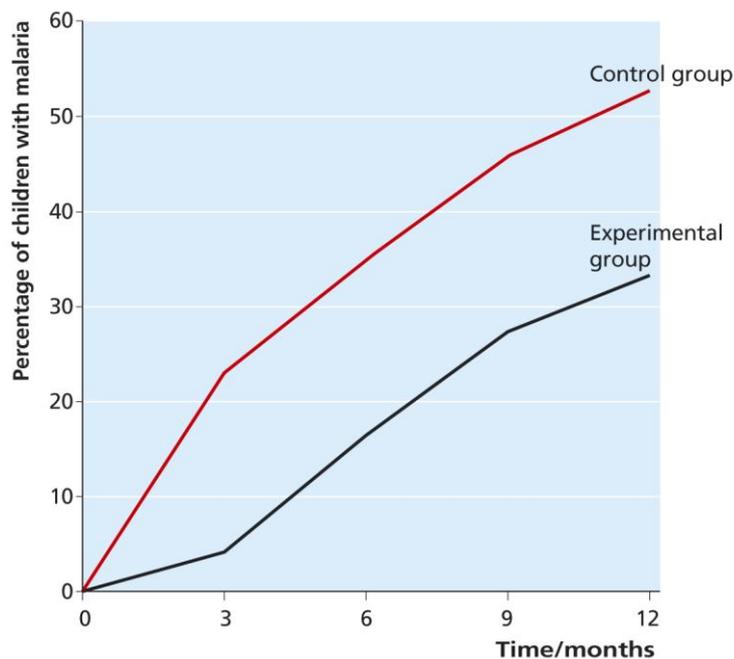
2 (a) The children enrolled for this trial were randomly divided into the two groups. Explain why it was important that they were divided randomly. (1 mark)

(b) The doctors carrying out the trial did not know which treatment the children had received until after they had analysed the results. Explain why this was important. (1 mark)

3 Not storing the vaccine in a refrigerator at the correct temperature may have affected its efficiency. Suggest an explanation for this. (2 marks)

4 During this trial, 57 children died. The doctors conducting the trial did not think that this was a reason to stop the trial. Explain how they could use figures from the experimental group and the control group to justify this decision. (2 marks)

The graph shows some of the results from this trial.



5 The time on the x-axis of the graph starts 14 days after vaccination. Explain why the doctors only recorded the number of cases of malaria from 14 days after vaccination. (2 marks)

6 The doctors reported that there were some side effects from the malaria vaccine. Convulsions occurred in the 7 days after giving the vaccine at a rate of approximately 1 per 1000 doses. Although all children recovered, this was a higher rate than with the control group. Do you think that the trial should have been stopped because of this? Give a reason for your answer. (2 marks)

Suggested marking guidelines

These guidelines give an indication of what might be expected by way of answers. They are intended as a basis for discussion.

- 1** The amino acid sequences are antigens;
 Memory cells are made;
 On exposure to malarial parasite, the memory cells become active/produce antibodies/recognise the antigens;
 Rapidly produce antibodies/produce more antibodies;
 Antibodies destroy the malarial parasite;
 Herd effect/fewer infected people to pass on malaria; 5 max

This question involves straightforward factual recall of an area; however, many students experience considerable difficulty. It is worth encouraging students to use appropriate scientific terminology. In answering this type of question there are often too many references to 'remembering' and 'fighting'.

- 2 (a)** Avoids bias/avoids selecting particular children in a group; 1
(b) Results not influenced by doctors; 1

- 3** Likely to be too warm;
 May denature amino acid sequences/antigens/proteins in vaccine; 2

This is very much a 'suggest' question so accept other plausible answers relating to storing at higher temperatures.

- 4** Calculate percentage/proportion of children dying in each group;
 Should be no/little difference; 2

As there are different numbers of children in the experimental and control groups a percentage or proportion needs to be calculated.

- 5** The doctors were investigating the effects of the vaccine;
 Takes time for it to become effective/takes time for memory cells to be formed;
 Rules out already present; 2 max

- 6** No, because all children recovered;
 Without the vaccine, many more would have caught/would have died from malaria; 2