1.18 Human Defences, Vaccination and Drug Development: 1-hour Pack

AQA 8464 · Calculator allowed · about 60 minutes

Total Marks

Name: _____ Date: ____ / ____ / _____

Answer ALL questions. Show all your working.

Vaccination Coverage and Whooping Cough Cases

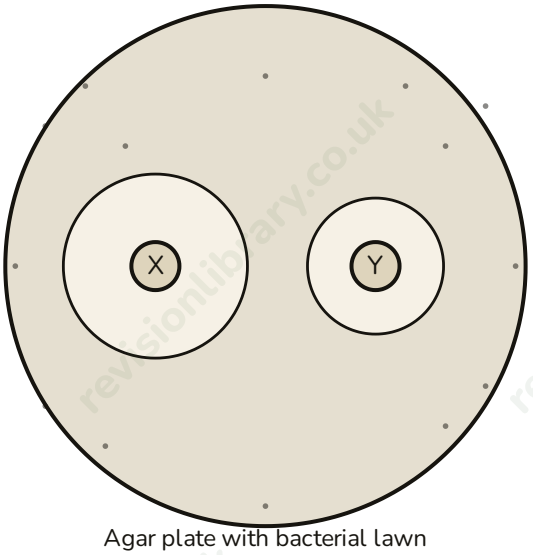
Original scenario written for Revision Library, styled on the format of UK public health vaccination-coverage reporting (e.g. UKHSA/NHS data summaries). No copied text or figures.

Whooping cough (pertussis) is a bacterial infection that can be serious in young babies. In one country, a national vaccination programme against whooping cough was introduced. Before the programme began, 84000 cases of whooping cough were recorded per year. Several years after the programme began, this fell to 3150 cases per year.

At a secondary school in the same country, 1500 students attend. School nurse records show that 88% of these students have received the MMR (measles, mumps and rubella) vaccine. Public health guidance states that at least 95% vaccination coverage is generally needed to achieve herd immunity against measles within a school-sized population.

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1 Required practical: investigating the effect of antibiotics on bacterial growth using agar plates. A student investigated the effectiveness of two antibiotics by placing paper discs soaked in antibiotic X and antibiotic Y onto an agar plate that had been spread with a lawn of a harmless species of bacterium. The plate was incubated, and the size of the clear zone (zone of inhibition) around each disc was measured after 48 hours.



Agar plate with bacterial lawn

(a) State two aseptic techniques the student should have used when setting up this investigation, and explain the purpose of each. **(2)**

(b) Suggest why the agar plate was incubated at a maximum of 25 C in the school laboratory, rather than at 37 C (normal human body temperature). **(2)**

(c) The clear zone (zone of inhibition) around disc X was circular, with a radius of 6 mm. Calculate the area of this zone of inhibition. Give your answer to 3 significant figures. **(3)**

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(d) The zone of inhibition around disc Y had an area of 78.5 mm^2. Using your answer to part (c), compare the effectiveness of antibiotics X and Y against this bacterium. **(2)**

(e) Suggest one way the reliability of this investigation could be improved, and evaluate why your suggestion would increase confidence in the conclusion. **(4)**

(Total for Question 1 is 13 marks)

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2 Before a new medicinal drug, such as a new painkiller, can be prescribed by doctors, it must go through an extensive testing and trialling process. Describe the main stages involved in developing and testing a new medicinal drug, from preclinical testing through to clinical trials.

(Total for Question 2 is 5 marks)

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3 Clinical trials of a new drug are often designed to include a placebo group and are carried out double-blind. Explain why a placebo is used, and why the trial is carried out double-blind.

(Total for Question 3 is 4 marks)

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4 A pharmaceutical company has developed a new painkiller and wants to bring it to market for doctors to prescribe. Evaluate the process the company must follow to test and trial this new painkiller before it can be prescribed by doctors, including reference to safety, effectiveness and appropriate dosage.

(Total for Question 4 is 6 marks)

5 Monoclonal antibodies have several important uses in medicine and research.

(a) Describe two different uses of monoclonal antibodies, explaining in each case how their specificity for one antigen makes that use possible. **(3)**

(b) Evaluate one limitation of using monoclonal antibodies to treat disease. **(2)**

(Total for Question 5 is 5 marks)

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6 Lymphocytes respond to specific pathogens by producing antibodies and antitoxins.

(a) Explain why a particular antibody will only bind to one specific type of antigen. **(2)**

(b) Describe the difference between the roles of antibodies and antitoxins when the body defends itself against a bacterial infection. **(3)**

(Total for Question 6 is 5 marks)

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7 Use the information in the source about whooping cough cases to answer this question. Calculate the percentage decrease in the number of whooping cough cases per year after the vaccination programme began. Give your answer to 3 significant figures.

(Total for Question 7 is 3 marks)

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8 Use the information in the source about MMR vaccination coverage at the school to answer this question.

(a) Calculate the number of students at the school who have NOT been vaccinated against MMR. **(2)**

(b) State and explain whether herd immunity against measles has been achieved at this school. **(2)**

(Total for Question 8 is 4 marks)

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Mark scheme · 1.18 Human Defences, Vaccination and Drug Development: 1-hour Pack

Question 1

(a) e.g. sterilise the Petri dishes, agar and equipment (for example, using an autoclave) before use - to kill any microorganisms already present, preventing contamination of the culture (oe; accept any one valid technique with a correct purpose) **B1**

(a) e.g. flame the neck of the bottle containing the bacterial culture (and the inoculating loop) immediately before and after use - to kill microorganisms in the air that could fall in and contaminate the culture, or that could escape (oe; accept any one different valid technique with a correct purpose) **B1**

(a) Answer: Any two of: sterilising equipment/agar before use; flaming the culture bottle neck and inoculating loop; working near a Bunsen flame; taping (not sealing) the lid - each to prevent unwanted microorganisms contaminating or escaping the culture.

(b) 37 C is the temperature at which many pathogens that could harm humans grow best/fastest (oe) **B1**

(b) incubating at a lower temperature (25 C or below) reduces the risk of culturing/growing such pathogens, while still allowing the (harmless) bacterium used in this investigation to grow (oe) **B1**

(b) Answer: Incubating below 25 C avoids growing conditions that favour pathogens that could infect humans (which grow best near body temperature, 37 C), keeping the investigation safer while still allowing the test bacterium to grow.

(c) area = $\pi \times r^2$ **M1**

(c) area = $\pi \times 6^2$ (= $\pi \times 36$) **M1**

(c) 113 mm^2 (awrt 113 mm^2) cao **A1**

(c) Answer: 113 mm^2

(d) antibiotic X produced a larger zone of inhibition (113 mm^2, allow ft from the candidate's answer to (c)) than antibiotic Y (78.5 mm^2) (oe; must show or state a clear numerical comparison) **B1**

(d) a larger zone of inhibition means the bacterium is more strongly inhibited by / more sensitive to that antibiotic, so antibiotic X is more effective against this bacterium than antibiotic Y (oe) **B1**

(d) Answer: Antibiotic X (zone area 113 mm^2) is more effective than antibiotic Y (zone area 78.5 mm^2), because a larger zone of inhibition shows the bacterium is more strongly inhibited by antibiotic X.

(e) valid improvement, e.g. test each antibiotic against more than one species/strain of bacterium (oe; accept: repeat the investigation several times for each antibiotic and calculate a mean zone area) **B1**

(e) reason linked to the chosen improvement, e.g. this shows whether the pattern (X more effective than Y) applies generally, rather than being specific to just one type of bacterium (oe; if repeats chosen: reduces the effect of anomalous results/random error on the mean) **B1**

(e) further valid related point, e.g. testing a wider range of antibiotic concentrations on the discs would show whether the difference depends on dose, not just the antibiotic used (oe) **B1**

(e) correctly links the suggested improvement to increased confidence in the conclusion (e.g. explicitly states that this would make it more certain that antibiotic X really is more effective, rather than the difference being due to chance or to the specific bacterium tested) (oe) **B1**

(e) Answer: Test each antibiotic against more than one species/strain of bacterium (or repeat the investigation and calculate a mean zone area for each antibiotic); this shows whether antibiotic X really is more effective in general, increasing confidence that the difference is real rather than due to chance or to the one bacterium tested.

Question 2

preclinical testing is carried out on cells and tissues in the laboratory, to test for toxicity and efficacy (oe) **B1**

preclinical testing is then carried out on live animals, to test for toxicity, an appropriate dosage, and efficacy in a whole living organism (oe) **B1**

if preclinical testing is successful, clinical trials on humans can begin, starting with a small number of healthy volunteers given a very low dose, to test for harmful side effects (oe) **B1**

if considered safe, trials continue on patients who have the illness, using a range of doses, to find the optimum dose that is most effective with the fewest side effects (oe) **B1**

the drug and trial results are peer reviewed by other scientists, and the drug must pass regulatory approval, before doctors can prescribe it (oe) **B1**

Answer: Preclinical testing on cells/tissues, then live animals, checks toxicity, dosage and efficacy; clinical trials on healthy volunteers at a low dose test safety, then patients are tested across a range of doses to find the optimum dose; results are peer reviewed and approved before the drug can be prescribed.

Question 3

a placebo is a substance that looks/tastes identical to the drug being tested but contains no active ingredient (oe) **B1**

comparing patients given the drug with patients given the placebo allows researchers to see whether the drug itself is responsible for any improvement, rather than the placebo effect or patients simply expecting to feel better (oe) **B1**

in a double-blind trial, neither the patient nor the doctor/researcher assessing them knows who has received the drug or the placebo until the trial ends (oe) **B1**

this reduces bias, because the doctor's or patient's expectations cannot influence how symptoms are reported or assessed (oe) **B1**

Answer: A placebo (identical in appearance but with no active ingredient) lets researchers separate the drug's real effect from the placebo effect; carrying out the trial double-blind, so neither patient nor assessor knows who received the drug, prevents expectation or bias from affecting the results.

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Question 4

Level 1 Basic, isolated statement(s) about testing a drug, for example a simple reference to preclinical or clinical testing. Little or no evaluation of why the process is needed. The answer may lack scientific detail or structure. **1-2**

Level 2 Clear description of most of the main stages of drug testing (preclinical and clinical), with some correct reference to features such as placebo use or double-blind design. Some attempt to evaluate why stages are necessary, though the reasoning may be incomplete or not fully linked together. **3-4**

Level 3 A detailed, logically structured description of the full testing and trialling process, from preclinical testing through to clinical trials, correctly referencing placebo use and double-blind design. A well-reasoned evaluation is given, clearly weighing the need for patient safety and reliable results against the time and cost of bringing a new drug to patients. **5-6**

Indicative content:

- Preclinical testing is carried out on cells and tissues in the laboratory, to check for toxicity before any human exposure.
- Preclinical testing is then carried out on live animals, to test for toxicity, an appropriate dosage range, and efficacy in a whole organism.
- Clinical trials begin with a small number of healthy human volunteers, given a very low dose, to check the drug does not cause harmful side effects.
- If safe, trials continue on patients with the condition, using a range of doses, to find the optimum dose that gives the greatest benefit with the fewest side effects.
- A placebo may be given to a control group so that the drug's real effect can be separated from the placebo effect or natural recovery.
- Trials are often double-blind, so neither the patient nor the doctor/researcher knows who has received the drug or placebo, reducing bias in the results.
- Large-scale trials involving many patients help to identify rare side effects and confirm the drug works across different types of patient.
- Volunteers and patients must give informed consent and can withdraw at any time, which protects patient welfare during testing.
- Results are peer reviewed by other scientists, and the drug must pass regulatory approval, before doctors can prescribe it.
- The lengthy, multi-stage process balances patient safety and reliable evidence of effectiveness against the delay and cost of bringing a new painkiller to patients who need it.

Question 5

(a) pregnancy testing - the antibody used binds specifically to hCG (a hormone found in the urine of pregnant women), producing a visible colour change/line if hCG is present (oe) **B1**

(a) cancer treatment/diagnosis - antibodies can be produced that bind specifically to antigens found only on cancer cells; they can carry a toxic drug, radioactive substance, or marker directly to the cancer cell without affecting normal healthy cells (oe) **B1**

(a) a further valid use, e.g. in research/laboratory diagnosis, to measure or detect the amount of a specific substance (such as a hormone or a pathogen's antigen) in a blood or other sample (oe); accept any two of these three uses, credited once each, up to 3 marks **B1**

(a) Answer: Any two of: pregnancy testing (antibody binds specifically to hCG); cancer diagnosis/treatment (antibody binds only to cancer-cell antigens, allowing targeted drug/radioactive delivery); laboratory diagnosis/research (antibody binds specifically to the substance being measured/detected). In each case, specificity for one antigen means only the target substance/cell is detected or affected.

(b) identifies a valid limitation, e.g. monoclonal antibodies (originally produced using mouse cells) can trigger an immune/allergic reaction in the patient, because the patient's immune system recognises them as foreign (oe; accept other valid limitations, e.g. high cost/time of production) **B1**

(b) expands with a linked evaluative consequence, e.g. this can cause side effects such as fever, can limit the dose that can safely be given, or requires the antibody to be 'humanised', increasing production cost and time (oe) **B1**

(b) Answer: Monoclonal antibodies can be recognised as foreign by the patient's immune system (as they are often produced using mouse cells), triggering side effects or an allergic reaction; this can limit the safe dose or require costly, time-consuming 'humanising' of the antibody before use.

Question 6

(a) the antibody has a binding site with a shape that is complementary to the antigen (oe) **B1**

(a) only an antigen with a matching/complementary shape can bind to that antibody (oe) **B1**

(a) Answer: An antibody's binding site has a shape complementary to one specific antigen, so it will only bind to (and be triggered by) that matching antigen.

(b) antibodies bind to antigens on the surface of the pathogen itself (oe) **B1**

(b) this can label the pathogen for destruction by phagocytes, or cause pathogens to clump together (agglutinate) (oe) **B1**

(b) antitoxins instead bind to and neutralise toxins released by the pathogen, making them harmless, rather than acting on the pathogen itself (oe) **B1**

(b) Answer: Antibodies bind to antigens on the pathogen itself (marking it for destruction, or causing it to clump); antitoxins instead bind to and neutralise the toxins the pathogen releases.

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Question 7

decrease = 84000 - 3150 (= 80850)	**M1**
percentage decrease = (decrease / original) x 100 = (80850 / 84000) x 100	**M1**
96.3% (awrt 96.2-96.3%) cao	**A1**

Answer: 96.3% (accept 96.2% to 96.3%)

Question 8

(a) unvaccinated = 100% - 88% = 12%; number = 12% of 1500 (= 0.12 x 1500)	**M1**
(a) 180 (students) cao	**A1**

(a) Answer: 180 students

(b) no, herd immunity has not been achieved (ft: must be consistent with the coverage figure used, but the correct answer is 'no')	**B1**
(b) because the school's vaccination coverage (88%) is below the 95% threshold stated as being needed for herd immunity (oe; must compare both figures)	**B1**

(b) Answer: No - the school's coverage of 88% is below the 95% threshold needed for herd immunity.

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