B3bD Human Defences, Vaccination and Drug Development: Exam Drill

AQA 8464 · Calculator allowed · about 90 minutes

Total Marks

Name: _____ Date: ____ / ____ / _____

Answer ALL questions. Show all your working.

1 Pathogens can cause disease in humans.

(a) Give the definition of the term 'pathogen'. **(1)**

(b) Name two types of pathogen. **(2)**

(Total for Question 1 is 3 marks)

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2 Describe two physical or chemical barriers in the human body that help prevent pathogens entering.

(a) Describe one physical barrier and how it stops pathogens. **(1)**

(b) Describe one chemical barrier and how it helps prevent infection. **(1)**

(Total for Question 2 is 2 marks)

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3 Vaccination can protect individuals and populations.

(a) Explain how vaccination leads to immunity in an individual. Give the immunological steps. **(3)**

(Total for Question 3 is 3 marks)

4 Antibodies bind specifically to antigens.

(a) Explain what is meant by the specificity of an antibody. **(1)**

(b) Give one consequence of antibody specificity for vaccine design. **(1)**

(Total for Question 4 is 2 marks)

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5 A community study recorded cases in a recent outbreak. 1 200 people received Vaccine X and 30 of these still developed the disease. In the unvaccinated group of 600 people, 60 developed the disease. Calculate the vaccine efficacy as a percentage using the formula: efficacy = (attack rate unvaccinated - attack rate vaccinated) / attack rate unvaccinated x 100.

(a) Show your working and give the vaccine efficacy to 3 significant figures. **(3)**

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(Total for Question 5 is 3 marks)

6 Required-practical style: A student investigates the effect of different concentrations of antiseptic solution on the number of bacteria colonies growing on agar plates. Five concentrations were tested: 0% (control), 1%, 2%, 4% and 8%. For each concentration the student spread a known volume of the same bacterial suspension on three plates, applied the antiseptic, incubated for 24 hours at 25 degrees C and then counted colonies. The mean colony counts recorded were: 0% = 360, 1% = 220, 2% = 140, 4% = 80, 8% = 30. The student was careful to use the same volume each time but later realised the pipette used for the 4% plates delivered 10% less volume by accident.

(a) State two control variables the student should keep the same to make this a fair test. **(2)**

(b) Explain how the pipette error for the 4% plates is likely to affect the mean colony count recorded for 4% and whether this introduces bias in comparing concentrations. **(2)**

(c) Suggest one practical improvement the student could make to reduce the impact of such pipetting errors on the final conclusions. **(1)**

(Total for Question 6 is 5 marks)

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7 A pharmaceutical company is developing a new antiviral. In early trials they measure the concentration of drug in the blood of volunteers at intervals. At time 0 the concentration is 12 mg per litre. After 2 hours it is 9.6 mg per litre. Assume first-order elimination and that concentration halves after a fixed time. Use the approximation that for small time intervals the percentage decrease is consistent.

(a) Calculate the percentage decrease in concentration over the 2 hours. Give your answer to 3 significant figures. **(2)**

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(b) Using the 20.0% decrease every 2 hours as an approximation, estimate the concentration after a further 4 hours (total 6 hours). Show working and give answer to 3 significant figures. **(2)**

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8 Data analysis: A trial compared two dosing schedules of a vaccine: single dose and two doses given 4 weeks apart. The table shows the mean antibody titre (arbitrary units) measured 6 weeks after first dose. Single dose group mean = 30 units (n = 50, standard deviation 12). Two-dose group mean = 85 units (n = 48, standard deviation 18).

(a) State two pieces of evidence from the data that suggest the two-dose schedule produces a stronger immune response. **(2)**

(b) Suggest one further statistical or experimental piece of information that would help determine whether the difference is statistically significant. **(2)**

(Total for Question 8 is 4 marks)

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9 Extended response: The development of new drugs is a lengthy process involving discovery, preclinical testing, clinical trials phases 1 to 3, and then regulatory approval and monitoring. Explain why it is important to have multiple phases of clinical trials and post-approval monitoring when developing new drugs. In your answer consider safety, efficacy, sample size, different populations and rare side effects.

(Total for Question 9 is 6 marks)

10 Error analysis: A published small study claimed that a new nasal vaccine reduced infection by 50% compared to control. The study had 20 participants in each group. In the vaccine group 6 people were infected; in the control group 12 were infected. A student comments that the study is unreliable. Explain two reasons based on the data and study design that support the student's comment.

(a) Give one reason based on sample size or variability. Refer to the numbers given. **(2)**

(b) Give another reason related to study design or missing information that weakens the claim. **(2)**

(Total for Question 10 is 4 marks)

Mark scheme · B3bD Human Defences, Vaccination and Drug Development: Exam Drill

Question 1

- (a) **B1** an organism or agent that causes disease in another organism, oe
- **(a) Answer: An organism or agent that causes disease in another organism.**
- (b) **B1** first correct type: bacteria, virus, fungus, protozoan, or parasite
- (b) **B1** second correct type: bacteria, virus, fungus, protozoan, or parasite (different to first)
- **(b) Answer: Any two of: bacteria; virus; fungus; protozoan; parasite.**

Question 2

- (a) **B1** description of a physical barrier with its protective action, e.g. skin forms a continuous barrier that prevents entry of microbes
- **(a) Answer: Skin forms a continuous barrier that prevents microbes entering the body.**
- (b) **B1** description of a chemical barrier with its protective action, e.g. hydrochloric acid in the stomach kills many ingested microbes
- **(b) Answer: Hydrochloric acid in the stomach kills many microbes in swallowed food, preventing infection.**

Question 3

- (a) **M1** vaccine introduces antigen or weakened/killed pathogen so immune system recognises it
- (a) **A1** activates B cells to produce specific antibodies against the antigen
- (a) **A1** memory B cells and T cells are produced so a faster response occurs on later infection, cao
- **(a) Answer: Vaccine introduces antigen so the immune system recognises it; B cells produce specific antibodies; memory B and T cells form so a faster stronger response occurs on later exposure.**

Question 4

- (a) **B1** antibody has a binding site that fits a particular antigen shape; binds only to that antigen or very similar ones
- **(a) Answer: An antibody has a binding site complementary to a particular antigen shape so it binds only to that antigen or very similar ones.**
- (b) **B1** vaccine must present the correct antigen(s) to induce protective antibodies; e.g. change in antigen may reduce vaccine effectiveness
- **(b) Answer: Vaccines must present the correct antigen so produced antibodies match the pathogen; antigen changes can reduce vaccine effectiveness.**

Question 5

- (a) **M1** calculates attack rates: vaccinated 30/1200 = 0.025 and unvaccinated 60/600 = 0.10
- (a) **M1** substitutes into formula: (0.10 - 0.025) / 0.10
- (a) **A1** 75.0% cao
- **(a) Answer: 75.0%**

Question 6

- (a) **B1** same incubation temperature
- (a) **B1** same incubation time or same initial bacterial concentration/volume spread, oe
- **(a) Answer: Any two of: same incubation temperature; same incubation time; same initial bacterial suspension concentration; same volume spread on plates.**
- (b) **M1** recognises that 10% less volume means fewer bacteria were spread, so colony counts will be artificially lower
- (b) **A1** concludes this makes the 4% result appear more effective than it is, introducing bias when comparing concentrations, oe
- **(b) Answer: The pipette delivered 10% less volume so fewer bacteria were spread and colony counts for 4% will be artificially lower; this makes the 4% appear more effective and introduces bias when comparing concentrations.**
- (c) **B1** use a calibrated pipette or repeat measurements and discard anomalous plates or increase number of replicates, oe
- **(c) Answer: Use a calibrated pipette and increase replicates (more plates per concentration) so anomalous volumes have less effect.**

Question 7

- (a) **M1** calculates percentage decrease: (12 - 9.6) / 12 x 100
- (a) **A1** 20.0% cao
- **(a) Answer: 20.0%**
- (b) **M1** applies successive decreases: after 2h 9.6, after 4h 9.6 x 0.80 = 7.68, after 6h 7.68 x 0.80
- (b) **A1** 6.14 mg per litre cao
- **(b) Answer: 6.14 mg per litre**

Question 8

- (a) **B1** mean antibody titre is higher for two-dose group (85 vs 30)
- (a) **B1** both groups have reasonably large sample sizes (n = 48 and n = 50), so the difference is likely to be meaningful, oe
- **(a) Answer: Two-dose group has a much higher mean titre (85 vs 30); both groups have similar sample sizes (n = 48 and 50) so the difference is likely to be meaningful.**
- (b) **B1** provide a p value from an appropriate test (t test) or provide confidence intervals for the means
- (b) **B1** or show raw data distribution or do a statistical test to compare means (e.g. t test) oe
- **(b) Answer: Provide a p value from a t test or confidence intervals for the means, or show the raw data distribution to assess overlap.**

Question 9

- **Level 3** (5-6): Detailed explanation linking multiple trial phases to ensuring safety and efficacy; considers increasing sample size, testing in varied populations, detection of rare side effects and the role of post-approval monitoring. Clear, organised reasoning and relevant examples.
- **Level 2** (3-4): Some explanation covering at least two reasons (for example safety and efficacy or sample size and rare side effects) with limited development and some linking between points.
- **Level 1** (1-2): Simple statements such as 'trials check safety' with minimal or no explanation and little linking.
- **Indicative content:**
  - Phase 1 uses small numbers to check safety and dosage; detects common short-term side effects
  - Phase 2 tests efficacy and side effects in patients and refines dose, with more participants
  - Phase 3 uses large, diverse populations to detect less common side effects and confirm efficacy across groups
  - Larger samples increase the chance of finding rare adverse effects and reveal variation in response between ages, sexes or comorbidities
  - Post-approval monitoring (phase 4) detects very rare or long-term side effects and real-world effectiveness
  - Multiple phases reduce risk of harm, ensure benefit outweighs risk, and provide data for regulators to make informed decisions

Question 10

- (a) **M1** identifies small sample size (n = 20 per group) and notes this increases random variation
- (a) **A1** concludes that with only 20 per group the observed difference (6 vs 12) may be due to chance and is not reliably generalisable, oe
- **(a) Answer: The groups are very small (20 each) so random variation is large; the observed difference (6 infected vs 12) could be due to chance and may not be generalisable.**
- (b) **B1** lack of information about randomisation, blinding or participant characteristics
- (b) **B1** or absence of statistical significance testing or confidence intervals to show the result is not due to chance
- **(b) Answer: There is no information on randomisation, blinding or participant characteristics and no statistical test or confidence intervals; these omissions mean bias or confounding could explain the apparent 50% reduction.**