Higher Human Biology:
Course content change comparison

This edition: February 2018, version 1.0

Key areas	Depth of knowledge required	Changes to content
Human cells		
1 Division and differentiation in human cells		Former key areas 1.1 (a) and 1.1 (d) combined.
(a) Division of somatic and germline cells.	A somatic cell is any cell in the body other than cells involved in reproduction. Germline cells are gametes (sperm and ova) and the stem cells that divide to form gametes.	Minor rewording for clarification. Clarification of required depth of knowledge.
Somatic stem cells divide by mitosis to form more somatic cells.		
Germline stem cells divide by mitosis and by meiosis.		
Division by mitosis produces more germline stem cells.	The nucleus of a germline stem cell can divide by mitosis to maintain the diploid chromosome number. Diploid cells have 23 pairs of homologous chromosomes.	Reference to mutations in germline cells removed.
Division by meiosis produces haploid gametes.	The nucleus of a germline stem cell can divide by meiosis. It undergoes two divisions, firstly separating homologous chromosomes and secondly separating chromatids. Haploid gametes contain 23 single chromosomes. Further detail of the process of meiosis is not required.	

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(b) Cellular differentiation. Cellular differentiation is the process by which a cell expresses certain genes to produce proteins characteristic for that type of cell. This allows a cell to carry out specialised functions. Embryonic and tissue stem cells. Cells in the very early embryo can differentiate into all the cell types that make up the individual and so are pluripotent. Tissue stem cells are involved in the growth, repair and renewal of the cells found in that tissue. They are multipotent.	All the genes in embryonic stem cells can be switched on so these cells can differentiate into any type of cell. Tissue stem cells are multipotent as they can differentiate into all of the types of cell found in a particular tissue type. For example, blood stem cells located in bone marrow can give rise to red blood cells, platelets, phagocytes and lymphocytes.	Former key areas 1.1 (b) and 1.1 (c) combined. Minor rewording for clarification. Clarification of required depth of knowledge. Reference to body tissue types and organs removed.
(c) Therapeutic and research uses of stem cells. Therapeutic uses involve the repair of damaged or diseased organs or tissues. Research uses involve stem cells being used as model cells to study how diseases develop or being used for drug testing.	The therapeutic uses of stem cells should be exemplified by how they are used in corneal repair and the regeneration of damaged skin. Stem cells from the embryo can self-renew, under the right conditions, in the lab. Stem cell research provides information on how cell processes such as cell growth, differentiation and gene regulation work.	Formerly key area 1.1 (e). Minor rewording for clarification. Clarification of required depth of knowledge.

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The ethical issues of using embryonic stem cells.	Use of embryonic stem cells can offer effective treatments for disease and injury; however, it involves destruction of embryos.	Regulation of stem cell use removed.
(d) Cancer cells divide excessively because they do not respond to regulatory signals. This results in a mass of abnormal cells called a tumour. Cells within the tumour may fail to attach to each other, spreading through the body where they may form secondary tumours.		Formerly key area 1.1 (f). Minor rewording for clarification. No change to content.
2 Structure and replication of DNA (a) Structure of DNA — nucleotides (deoxyribose sugar, phosphate and base), sugar–phosphate backbone, base pairing (adenine–thymine and guanine–cytosine), by hydrogen bonds and double stranded antiparallel structure, with deoxyribose and phosphate at 3' and 5' ends of each strand respectively, forming a double helix.	The base sequence of DNA forms the genetic code.	Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
		Former key area 1.2 (b) removed.
(b) Replication of DNA by DNA polymerase and primers. DNA polymerase adds DNA nucleotides, using complementary base pairing, to the deoxyribose (3') end of the new DNA strand	Prior to cell division, DNA is replicated by a DNA polymerase. DNA polymerase needs primers to start replication. A primer is a short strand of nucleotides which binds to the 3' end of the template DNA strand allowing polymerase to add DNA nucleotides. DNA is unwound and hydrogen bonds between bases are broken to form two template strands. DNA polymerase can only add DNA nucleotides in one	Formerly key area 1.2 (c). Reworded for clarification. Clarification of required depth of knowledge.

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which is forming. Fragments of DNA are joined together by ligase.	direction resulting in the leading strand being replicated continuously and the lagging strand replicated in fragments.	The term 'unzipped' removed.
(c) Polymerase chain reaction (PCR) amplifies DNA using complementary primers for specific target sequences. Repeated cycles of heating and cooling amplify the target region of DNA. Practical applications of PCR.	In PCR, primers are short strands of nucleotides which are complementary to specific target sequences at the two ends of the region of DNA to be amplified. DNA is heated to between 92 and 98 °C to separate the strands. It is then cooled to between 50 and 65 °C to allow primers to bind to target sequences. It is then heated to between 70 and 80 °C for heat-tolerant DNA polymerase to replicate the region of DNA. PCR can amplify DNA to help solve crimes, settle paternity suits and diagnose genetic disorders.	Formerly key area 1.5 (b). Minor rewording for clarification. Clarification of required depth of knowledge. Use of DNA probes and fluorescent labelling removed. Identification through comparison of regions of the genome removed.
3 Gene expression (a) Gene expression involves the transcription and translation of DNA sequences. Transcription and translation involves three types of RNA (mRNA, tRNA and rRNA).	Only a fraction of the genes in a cell are expressed. RNA is single stranded and is composed of nucleotides containing ribose sugar, phosphate and one of four bases: cytosine, guanine, adenine and uracil.	Former key areas 1.3 (a) and 1.3 (b) combined. Structure of tRNA from key area 1.3(d) included here. Information on phenotype determination moved to key area 1.3 (e).

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Messenger RNA (mRNA) carries a copy of the DNA code from the nucleus to the ribosome. Transfer RNA (tRNA) folds due to complementary base pairing. Each tRNA molecule carries its specific amino acid to the ribosome. Ribosomal RNA (rRNA) and proteins form the ribosome.	mRNA is transcribed from DNA in the nucleus and translated into proteins by ribosomes in the cytoplasm. Each triplet of bases on the mRNA molecule is called a codon and codes for a specific amino acid. A tRNA molecule has an anticodon (an exposed triplet of bases) at one end and an attachment site for a specific amino acid at the other end.	Influence of intra- and extra-cellular environmental factors removed. Minor rewording for clarification. Clarification of required depth of knowledge.
(b) The role of RNA polymerase in transcription of DNA into primary mRNA transcripts. RNA splicing forms a mature mRNA transcript. The introns of the primary transcript are non-coding regions and are removed. The exons are coding regions and are joined together to form the mature transcript.	RNA polymerase moves along DNA unwinding the double helix and breaking the hydrogen bonds between the bases. RNA polymerase synthesises a primary transcript of mRNA from RNA nucleotides by complementary base pairing. Uracil in RNA is complementary to adenine. The order of the exons is unchanged during splicing.	Formerly key area 1.3 (c). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

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(c) tRNA is involved in the translation of mRNA into a polypeptide at a ribosome. Translation begins at a start codon and ends at a stop codon. Anticodons bond to codons by complementary base pairing, translating the genetic code into a sequence of amino acids. Peptide bonds join the amino acids together. Each tRNA then leaves the ribosome as the polypeptide is formed.		Formerly key area 1.3 (d). Minor rewording for clarification. Structure of tRNA moved to key area 1.3 (a).
(d) Different proteins can be expressed from one gene, as a result of alternative RNA splicing. Different mature mRNA transcripts are produced from the same primary transcript depending on which exons are retained.		Formerly key area 1.3 (e). Minor rewording for clarification. Post-translational modification removed.
(e) Amino acids are linked by peptide bonds to form polypeptides. Polypeptide chains fold to form the three-dimensional shape of a protein, held together by hydrogen bonds and other interactions between individual amino acids. Proteins have a large variety of shapes which determines their functions. Phenotype is determined by proteins produced as the result of gene expression.	Details of other interactions and levels of protein structure are not required. Environmental factors also influence phenotype.	Former key area 1.4 (a) and part of 1.3 (a) combined. Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

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4 Mutations (a) Mutations are changes in the DNA that can result in no protein or an altered protein being synthesised.		New key area heading. Formerly part of key area 1.4 (b). Minor rewording for clarification. No change to content.
(b) Single gene mutations involve the alteration of a DNA nucleotide sequence as a result of the substitution, insertion or deletion of nucleotides. Nucleotide substitutions — missense, nonsense and splice-site mutations. Nucleotide insertions or deletions result in frame-shift mutations.	Missense mutations result in one amino acid being changed for another. This may result in a non-functional protein or have little effect on the protein. Nonsense mutations result in a premature stop codon being produced which results in a shorter protein. Splice-site mutations result in some introns being retained and/or some exons not being included in the mature transcript. Frame-shift mutations cause all of the codons and all of the amino acids after the mutation to be changed. This has a major effect on the structure of the protein produced.	Formerly part of key area 1.4 (b). Minor rewording for clarification. Clarification of required depth of knowledge provided. Insertions or deletions resulting in the expansion of a nucleotide sequence repeat removed.
(c) Chromosome structure mutations — duplication, deletion, inversion and translocation.	Duplication is where a section of a chromosome is added from its homologous partner. Deletion is where a section of a chromosome is	Formerly part of key area 1.4 (b). Minor rewording for clarification. Clarification of required depth of knowledge.

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The substantial changes in chromosome mutations often make them lethal.	removed. Inversion is where a section of chromosome is reversed. Translocation is where a section of a chromosome is added to a chromosome, not its homologous partner.	All four chromosome structure mutations required.
5 Human genomics (a) The genome of an organism is its entire hereditary information encoded in DNA. A genome is made up of genes and other DNA sequences that do not code for proteins. In genomic sequencing the sequence of nucleotide bases can be determined for individual genes and entire genomes.	Computer programs can be used to identify base sequences by looking for sequences similar to known genes. To compare sequence data, computer and statistical analyses (bioinformatics) are required.	Reworded for clarification. Clarification of required depth of knowledge provided. Section on systematics removed.
		Former key area 1.5 (b) moved to key area 1.2 (c).
(b) An individual's genome can be analysed to predict the likelihood of developing certain diseases. Pharmacogenetics and personalised medicine.	Pharmacogenetics is the use of genome information in the choice of drugs. An individual's personal genome sequence can be used to select the most effective drugs and dosage to treat their disease (personalised medicine).	Formerly part of key area 1.5 (a). Minor rewording for clarification. Clarification of required depth of knowledge provided. No change to content.

Key areas	Depth of knowledge required	Changes to content
6 Metabolic pathways (a) Metabolic pathways are integrated and controlled pathways of enzyme-catalysed reactions within a cell. Metabolic pathways can have reversible steps, irreversible steps and alternative routes. Reactions within metabolic pathways can be anabolic or catabolic. Anabolic reactions build up large molecules from small molecules and require energy. Catabolic reactions break down large molecules into smaller molecules and release energy.		Minor rewording for clarification. No change to content.
(b) Metabolic pathways are controlled by the presence or absence of particular enzymes and the regulation of the rate of reaction of key enzymes. Induced fit and the role of the active site of an enzyme in affecting activation energy and the affinity of the substrate and products for the active site. The effects of substrate and product concentration on the direction and rate of enzyme reactions.	Induced fit occurs when the active site changes shape to better fit the substrate after the substrate binds. The substrate molecule(s) have a high affinity for the active site and the subsequent products have a low affinity allowing them to leave the active site. Some metabolic reactions are reversible and the presence of a substrate or the removal of a product will drive a sequence of reactions in a particular direction.	Minor rewording for clarification. Clarification of required depth of knowledge. Control of regulation by intra- and extra-cellular signal molecules removed. Reference to groups of enzymes and multi-enzyme complexes removed.

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Control of metabolic pathways through competitive, non-competitive and feedback inhibition of enzymes.	Competitive inhibitors bind at the active site preventing the substrate from binding. Competitive inhibition can be reversed by increasing substrate concentration. Non-competitive inhibitors bind away from the active site but change the shape of the active site preventing the substrate from binding. Non-competitive inhibition cannot be reversed by increasing substrate concentration. Feedback inhibition occurs when the end-product in the metabolic pathway reaches a critical concentration. The end-product then inhibits an earlier enzyme, blocking the pathway, and so prevents further synthesis of the end-product.	
		Former key area 1.7 (a) removed.
7 Cellular respiration (a) Metabolic pathways of cellular respiration. Glycolysis is the breakdown of glucose to pyruvate in the cytoplasm. ATP is required for the phosphorylation of glucose and intermediates during the energy investment phase of glycolysis. This leads to the generation of more ATP during the energy pay-off stage and results in a net gain of ATP. In aerobic conditions pyruvate is broken down		Former key areas 1.7 (b) and 1.7 (c) combined. Reworded for clarification. The role of ATP in the transfer of energy moved to 1.7 (c). The role of phosphofructokinase removed.

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to an acetyl group that combines with coenzyme A forming acetyl coenzyme A. In the citric acid cycle the acetyl group from acetyl coenzyme A combines with oxaloacetate to form citrate. During a series of enzyme controlled steps, citrate is gradually converted back into oxaloacetate which results in the generation of ATP and release of carbon dioxide. The citric acid cycle occurs in the matrix of the mitochondria. Dehydrogenase enzymes remove hydrogen ions and electrons and pass them to the coenzyme NAD, forming NADH. This occurs in both glycolysis and the citric acid cycle. The hydrogen ions and electrons from NADH are passed to the electron transport chain on the inner mitochondrial membrane.		Coenzyme FAD and the formation of $FADH_2$ removed. Electrons being referred to as 'high energy' removed.
(b) ATP synthesis — electrons are passed along the electron transport chain releasing energy. This energy allows hydrogen ions to be pumped across the inner mitochondrial membrane. The flow of these ions back through the membrane protein ATP synthase results in the production of ATP.	The electron transport chain is a series of carrier proteins attached to the inner mitochondrial membrane.	Formerly key area 1.7 (d). Reworded for clarification. Clarification of required depth of knowledge.

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Finally, hydrogen ions and electrons combine with oxygen to form water.		Substrates for respiration removed. Regulation of the pathways of cellular respiration by feedback inhibition removed.
(c) The role of ATP in the transfer of energy.	ATP is used to transfer energy to cellular processes which require energy.	Formerly part of key area 1.7 (a). Clarification of required depth of knowledge.
		Former key area 1.8 (a) removed.
8 Energy systems in muscle cells (a) Lactate metabolism. During vigorous exercise, the muscle cells do not get sufficient oxygen to support the electron transport chain. Under these conditions, pyruvate is converted to lactate. This conversion involves the transfer of hydrogen from the NADH produced during glycolysis to pyruvate in order to produce lactate. This regenerates the NAD needed to maintain ATP production through glycolysis. Lactate accumulates and muscle fatigue occurs. The oxygen debt is repaid when exercise is complete. This allows respiration to provide the energy to convert lactate back to pyruvate and glucose in the liver.		Formerly key area 1.8 (b). Lactic acid now referred to as lactate. Reworded for clarification.

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(b) Types of skeletal muscle fibres. Slow twitch muscle fibres contract relatively slowly, but can sustain contractions for longer. They are useful for endurance activities such as long distance running, cycling or cross-country skiing. Fast twitch muscle fibres contract relatively quickly, over short periods. They are useful for activities such as sprinting or weightlifting. Most human muscle tissue contains a mixture of both slow and fast twitch muscle fibres. Athletes show distinct patterns of muscle fibres that reflect their sporting activities.	Slow twitch muscle fibres rely on aerobic respiration to generate ATP and have many mitochondria, a large blood supply and a high concentration of the oxygen-storing protein myoglobin. The major storage fuel of slow twitch muscle fibres is fats. Fast twitch muscle fibres can generate ATP through glycolysis only and have fewer mitochondria and a lower blood supply compared to slow twitch muscle fibres. The major storage fuel of fast twitch muscle fibres is glycogen.	Formerly key area 1.8 (c). Minor rewording for clarification. Clarification of required depth of knowledge provided. No change to content.

Key areas	Depth of knowledge required	Changes to content
Physiology and health		
1 Gamete production and fertilisation (a) Gamete production in the testes. Testes produce sperm in the seminiferous tubules and testosterone in the interstitial cells. The prostate gland and seminal vesicles secrete fluids that maintain the mobility and viability of the sperm.		New key area heading. Minor rewording for clarification. No change to content.
(b) Gamete production in the ovaries. The ovaries contain immature ova in various stages of development. Each ovum is surrounded by a follicle that protects the developing ovum and secretes hormones.		Minor rewording for clarification. No change to content.
(c) Fertilisation. Mature ova are released into the oviduct where they may be fertilised by sperm to form a zygote.		Minor rewording for clarification. No change to content.
2 Hormonal control of reproduction (a) Hormonal influence on puberty.	The pituitary gland is stimulated to release follicle stimulating hormone (FSH), luteinising hormone (LH) or interstitial cell stimulating hormone (ICSH) by a releaser hormone produced in the hypothalamus. This triggers the onset of puberty.	Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
(b) Hormonal control of sperm production.	FSH promotes sperm production and ICSH stimulates the production of testosterone. Testosterone also stimulates sperm production and activates the prostate gland and seminal vesicles. Negative feedback control of testosterone by FSH and ICSH.	Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

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(c) Hormonal control of the menstrual cycle. The menstrual cycle takes approximately 28 days with the first day of menstruation regarded as day one of the cycle. FSH stimulates the development of a follicle and the production of oestrogen by the follicle in the follicular phase. Oestrogen stimulates proliferation of the endometrium preparing it for implantation, and affects the consistency of cervical mucus making it more easily penetrated by sperm. Peak levels of oestrogen stimulate a surge in the secretion of LH. This surge in LH triggers ovulation. In the luteal phase the follicle develops into a corpus luteum which secretes progesterone. Progesterone promotes further development and vascularisation of the endometrium preparing it for implantation if fertilisation occurs. The negative feedback effect of the ovarian hormones on the pituitary gland and the secretion of FSH and LH prevent further follicles from developing. The lack of LH leads to degeneration of the corpus luteum with a subsequent drop in progesterone levels leading to menstruation.	Interpretation of graphs showing changes in FSH, LH, oestrogen and progesterone concentrations throughout the menstrual cycle. Ovulation is the release of an egg (ovum) from a follicle in the ovary. It usually occurs around the mid-point of the menstrual cycle. If fertilisation does occur the corpus luteum does not degenerate and progesterone levels remain high.	Reworded for clarification. Clarification of required depth of knowledge. Use of the term blastocyst is no longer required.

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3 The biology of controlling fertility Infertility treatments and contraception are based on the biology of fertility. (a) Women show cyclical fertility leading to a fertile period. Men show continuous fertility. Identification of the fertile period.	Women are only fertile for a few days during each menstrual cycle. Men continually produce sperm in their testes so show continuous fertility. A woman's body temperature rises by around 0·5 °C after ovulation and her cervical mucus becomes thin and watery.	Former key areas 2.3 (a) and 2.3 (b) combined. Risks and ethics associated with fertility treatments removed. Minor rewording for clarification. Clarification of required depth of knowledge.
(b) Treatments for infertility. Stimulating ovulation. Ovulation is stimulated by drugs that prevent the negative feedback effect of oestrogen on FSH secretion. Other ovulatory drugs mimic the action of FSH and LH. These drugs can cause super ovulation that can result in multiple births or be used to collect ova for in vitro fertilisation (IVF) programmes. Artificial insemination. Several samples of semen are collected over a period of time. Artificial insemination is particularly useful where the male has a low sperm count. If a partner is sterile a donor may be used to provide semen.		Formerly key area 2.3 (c). Clarification of required depth of knowledge. No change to content.

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Intra-cytoplasmic sperm injection (ICSI). If mature sperm are defective or very low in number, ICSI can be used. The head of the sperm is drawn into a needle and injected directly into the egg to achieve fertilisation. In vitro fertilisation (IVF). Surgical removal of eggs from ovaries after hormone stimulation. Incubation of zygotes and uterine implantation. The use of IVF in conjunction with pre-implantation genetic diagnosis (PGD) to identify single gene disorders and chromosomal abnormalities.	Eggs are mixed with sperm in a culture dish. The fertilised eggs are incubated until they have formed at least eight cells and are then transferred to the uterus for implantation.	
(c) Physical and chemical methods of contraception. Biological basis of physical methods used to prevent pregnancy. The oral contraceptive pill is a chemical method of contraception. It contains a combination of synthetic oestrogen and progesterone that mimics negative feedback preventing the release of FSH and LH from the pituitary gland. The progesterone-only (mini) pill causes thickening of the cervical mucus. The morning-after pill prevents ovulation or implantation.	Understanding of how the following physical methods prevent pregnancy — barriers, intra-uterine devices and sterilisation procedures. Change to effects of morning-after pill.	Formerly key area 2.3 (d). Reworded for clarification. Clarification of required depth of knowledge.

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4 Antenatal and postnatal screening A variety of techniques can be used to monitor the health of the mother, developing fetus and baby. (a) Antenatal screening Antenatal screening identifies the risk of a disorder so that further tests and a prenatal diagnosis can be offered. Ultrasound imaging. Pregnant women are given two ultrasound scans. Dating scans which determine pregnancy stage and due date are used with tests for marker chemicals which vary normally during pregnancy. Anomaly scans may detect serious physical abnormalities in the fetus. Blood and urine tests. Routine blood and urine tests are carried out throughout pregnancy to monitor the concentrations of marker chemicals. Diagnostic testing. Amniocentesis and chorionic villus sampling (CVS) and the advantages and disadvantages of their use. Cells from samples can be cultured to obtain sufficient cells to produce a karyotype to diagnose a range of conditions.	A dating scan takes place between 8 and 14 weeks and an anomaly scan between 18 and 20 weeks. Measuring a chemical at the wrong time could lead to a false positive result. An atypical chemical concentration can lead to diagnostic testing to determine if the fetus has a medical condition. CVS can be carried out earlier in pregnancy than amniocentesis, although it has a higher risk of miscarriage. A karyotype shows an individual's chromosomes arranged as homologous pairs.	Minor rewording for clarification. Clarification of required depth of knowledge.

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	In deciding to proceed with these tests, the element of risk will be assessed, as will the decisions the individuals concerned are likely to make if a test is positive.	Rhesus antibody testing removed.
(b) Analysis of patterns of inheritance in genetic screening and counselling. Patterns of inheritance in autosomal recessive, autosomal dominant, incomplete dominance and sex-linked recessive single gene disorders.	Draw, analyse and interpret family histories over three generations to follow patterns of inheritance in genetic disorders. Standard genetic terms and their related symbols should be used — alleles, dominant, recessive, homozygous, heterozygous, carriers, genotype, phenotype, autosomes and sex chromosomes.	Formerly part of key area 2.4 (b). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
(c) Postnatal screening. Diagnostic testing for phenylketonuria (PKU). In PKU a substitution mutation means that the enzyme which converts phenylalanine to tyrosine is non-functional.	Individuals with high levels of phenylalanine are placed on a restricted diet.	Formerly part of key area 2.4 (b). Minor rewording for clarification. Clarification of required depth of knowledge provided. Diagnostic testing for other metabolic disorders removed.
5 The structure and function of arteries, capillaries and veins (a) Blood circulates from the heart through the arteries to the capillaries then to the veins and back to the heart. There is a decrease in blood pressure as blood moves away from the heart.		Formerly part of key area 2.5 (a). Minor rewording for clarification. No change to content.

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(b) The structure and function of arteries, capillaries and veins: endothelium, central lumen, connective tissue, elastic fibres, smooth muscle and valves. The role of vasoconstriction and vasodilation in controlling blood flow.	The endothelium lining the central lumen of blood vessels is surrounded by layers of tissue. Arteries have an outer layer of connective tissue containing elastic fibres and a middle layer containing smooth muscle with more elastic fibres. The elastic walls of the arteries stretch and recoil to accommodate the surge of blood after each contraction of the heart. To control blood flow, the smooth muscle surrounding arteries can contract causing vasoconstriction or relax causing vasodilation. Capillaries allow exchange of substances with tissues through their thin walls. Veins have an outer layer of connective tissue containing elastic fibres but a much thinner muscular wall than arteries. They contain valves to prevent the backflow of blood.	Formerly part of key area 2.5 (a). Clarification of required depth of knowledge. No change to content.
(c) The exchange of materials between tissue fluid and cells through pressure filtration and the role of lymphatic vessels. Tissue fluid and blood plasma are similar in composition, with the exception of plasma proteins, which are too large to be filtered through the capillary walls.	Pressure filtration causes plasma to pass through capillary walls into the tissue fluid surrounding the cells. Tissue fluid supplies cells with glucose, oxygen and other substances. Carbon dioxide and other metabolic wastes diffuse out of the cells and into the tissue fluid to be excreted. Much of the tissue fluid returns to the blood. Lymphatic vessels absorb excess tissue fluid and return it as lymph to the circulatory system.	Formerly key area 2.5 (b). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

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6 The structure and function of the heart Blood flow through the heart and its associated blood vessels.		Blood flow through the heart from key area 2.6 (b) included here.
(a) Cardiac output and its calculation.	The volume of blood pumped through each ventricle per minute is the cardiac output. Cardiac output is determined by heart rate and stroke volume (CO = HR x SV). The left and right ventricles pump the same volume of blood through the aorta and pulmonary artery.	Minor rewording for clarification. Clarification of required depth of knowledge.
(b) The cardiac cycle. Functions of diastole, atrial systole and ventricular systole.	During diastole, blood returning to the atria flows into the ventricles. Atrial systole transfers the remainder of the blood through the atrio-ventricular (AV) valves to the ventricles. Ventricular systole closes the AV valves and pumps the blood out through the semi lunar (SL) valves to the aorta and pulmonary artery. In diastole, the higher pressure in the arteries closes the SL valves.	Clarification of required depth of knowledge.
Effect of pressure changes on atrio-ventricular (AV) and semi lunar (SL) valves.	The opening and closing of the AV and SL valves are responsible for the heart sounds heard with a stethoscope.	Blood flow through the heart moved to key area 2.6 (a).
(c) The structure and function of the cardiac conducting system. Control of contraction and timing by cells of the sino-atrial node (SAN) and transmission to the atrio-ventricular node (AVN).	The heartbeat originates in the heart itself. The auto-rhythmic cells of the sino-atrial node (SAN) or pacemaker, located in the wall of the right atrium, set the rate at which the heart contracts. The timing of cardiac muscle cell contraction is controlled by impulses from the SAN spreading through the atria causing atrial systole. They then travel to the atrio-ventricular node (AVN), located in the centre of the heart. Impulses from the AVN travel down fibres in the central wall of the heart and then up through the walls of the ventricles, causing ventricular systole.	Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

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Impulses in the heart generate currents that can be detected by an electrocardiogram (ECG). The medulla regulates the rate of the sino-atrial node through the antagonistic action of the autonomic nervous system (ANS). A sympathetic nerve releases noradrenaline which increases the heart rate, whereas a parasympathetic nerve releases acetylcholine which decreases the heart rate.	Interpretation of electrocardiograms (ECG) should involve calculation of heart rate and linking of the waves to atrial systole, ventricular systole and diastole.	
(d) Blood pressure changes in the aorta during the cardiac cycle. Measurement of blood pressure using a sphygmomanometer. Hypertension (high blood pressure) is a major risk factor for many diseases including coronary heart disease.	Blood pressure increases during ventricular systole and decreases during diastole. An inflatable cuff stops blood flow, in the artery, and deflates gradually. The blood starts to flow (detected by a pulse) at systolic pressure. The blood flows freely through the artery (and a pulse is not detected) at diastolic pressure. A typical blood pressure reading for a young adult is 120/80 mmHg.	Minor rewording for clarification. Clarification of required depth of knowledge. Change to typical blood pressure reading.
7 Pathology of cardiovascular disease (CVD) (a) Process of atherosclerosis, its effect on arteries and blood pressure.	Atherosclerosis is the accumulation of fatty material (consisting mainly of cholesterol, fibrous material and calcium) forming an atheroma or plaque beneath the	Minor rewording for clarification. Clarification of required depth of knowledge provided. No change to

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Atherosclerosis is the root cause of various cardiovascular diseases (CVD) — angina, heart attack, stroke and peripheral vascular disease.	endothelium. As the atheroma grows the artery thickens and loses its elasticity. The diameter of the lumen becomes reduced and blood flow becomes restricted resulting in increased blood pressure.	content.
(b) Thrombosis — endothelium damage, clotting factors and the role of prothrombin, thrombin, fibrinogen and fibrin. Thrombus formation and the formation and effects of an embolus. A thrombosis in a coronary artery may lead to a myocardial infarction (MI), commonly known as a heart attack. A thrombosis in an artery in the brain may lead to a stroke. Cells are deprived of oxygen leading to death of the tissues.	Atheromas may rupture damaging the endothelium. The damage releases clotting factors that activate a cascade of reactions resulting in the conversion of the enzyme prothrombin to its active form thrombin. Thrombin causes molecules of the plasma protein fibrinogen to form threads of fibrin. The fibrin threads form a meshwork that clots the blood, seals the wound and provides a scaffold for the formation of scar tissue. The formation of a clot (thrombus) is referred to as thrombosis. In some cases a thrombus may break loose forming an embolus which travels through the bloodstream until it blocks a blood vessel.	Reworded for clarification. Clarification of required depth of knowledge. No change to content.
(c) Causes and effects of peripheral vascular disorders. Peripheral vascular disease is narrowing of the arteries due to atherosclerosis of arteries other		Reworded for clarification. No change to content.

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than those of the heart or brain. The arteries to the legs are most commonly affected. Pain is experienced in the leg muscles due to a limited supply of oxygen. A deep vein thrombosis (DVT) is a blood clot that forms in a deep vein, most commonly in the leg. This can break off and result in a pulmonary embolism in the lungs.		
(d) Control of cholesterol levels in the body. Cholesterol is a type of lipid found in the cell membrane. It is also used to make the sex hormones — testosterone, oestrogen and progesterone. Cholesterol is synthesised by all cells, although 25% of total production takes place in the liver. A diet high in saturated fats or cholesterol causes an increase in cholesterol levels in the blood. Roles of high density lipoproteins (HDL) and low density lipoproteins (LDL). LDL receptors, negative feedback control and atheroma formation.	HDL transports excess cholesterol from the body cells to the liver for elimination. This prevents accumulation of cholesterol in the blood. LDL transports cholesterol to body cells. Most cells have LDL receptors that take LDL into the cell where it releases cholesterol. Once a cell has sufficient cholesterol a negative feedback system inhibits the synthesis of new LDL receptors and LDL circulates in the blood where it may deposit cholesterol in the arteries forming atheromas. A higher ratio of HDL to LDL will result in lower blood cholesterol and a reduced chance of atherosclerosis.	Familial hypercholesterolemia removed. Reworded for clarification. Clarification of required depth of knowledge.

Key areas	Depth of knowledge required	Changes to content
Ratios of HDL to LDL in maintaining health. The benefits of physical activity and a low fat diet. Reducing blood cholesterol through prescribed medications.	Regular physical activity tends to raise HDL levels. Dietary changes aim to reduce the levels of total fat in the diet and to replace saturated with unsaturated fats. Drugs such as statins reduce blood cholesterol by inhibiting the synthesis of cholesterol by liver cells.	Genetic screening of familial hypercholesterolemia and its treatments removed.
8 Blood glucose levels and obesity (a) Chronic elevated blood glucose levels lead to atherosclerosis and blood vessel damage.	Chronic elevation of blood glucose levels leads to the endothelium cells taking in more glucose than normal, damaging the blood vessels. Atherosclerosis may develop leading to cardiovascular disease, stroke or peripheral vascular disease. Small blood vessels damaged by elevated glucose levels may result in haemorrhage of blood vessels in the retina, renal failure or peripheral nerve dysfunction.	Clarification of required depth of knowledge. No change to content.
(b) Pancreatic receptors and the role of hormones in negative feedback control of blood glucose through insulin, glucagon and adrenaline.	Pancreatic receptors respond to raised blood glucose levels by increasing secretion of insulin from the pancreas. Insulin activates the conversion of glucose to glycogen in the liver decreasing blood glucose concentration. Pancreatic receptors respond to lowered blood glucose levels by increasing secretion of glucagon from the pancreas. Glucagon activates the conversion of glycogen to glucose in the liver increasing blood glucose concentration. During exercise and fight or flight responses, glucose concentrations in the blood are raised by adrenaline, released from the adrenal glands, stimulating glucagon secretion and inhibiting insulin secretion.	Formerly part of key area 2.8 (a). Clarification of required depth of knowledge. The term epinephrine removed.

Key areas	Depth of knowledge required	Changes to content
(c) Type 1 and type 2 diabetes. Type 1 diabetes usually occurs in childhood. A person with type 1 diabetes is unable to produce insulin and can be treated with regular doses of insulin. Type 2 diabetes typically develops later in life. The likelihood of developing type 2 diabetes is increased by being overweight. In type 2 diabetes, individuals produce insulin but their cells are less sensitive to it. This insulin resistance is linked to a decrease in the number of insulin receptors in the liver, leading to a failure to convert glucose to glycogen. In both types of diabetes, individual blood glucose concentrations will rise rapidly after a meal. The kidneys will remove some of this glucose, resulting in glucose appearing in urine. The glucose tolerance test is used to diagnose diabetes.	Testing urine for glucose is often used as an indicator of diabetes. The blood glucose concentrations of the individual are initially measured after fasting. The individual then drinks a glucose solution and changes in their blood glucose concentration are measured for at least the next two hours. The blood glucose concentration of a diabetic usually starts at a higher level than that of a non-diabetic. During the test a diabetic's blood glucose concentration increases to a much higher level than that of a non-diabetic and takes longer to return to its starting concentration.	Formerly part of key area 2.8 (a). Reworded for clarification. Clarification of required depth of knowledge. No change to content.

Key areas	Depth of knowledge required	Changes to content
(d) Obesity. Obesity is a major risk factor for cardiovascular disease and type 2 diabetes. Obesity is characterised by excess body fat in relation to lean body tissue such as muscle. Obesity may impair health. Body mass index (BMI) is commonly used to measure obesity but can wrongly classify muscular individuals as obese. Role of diet and exercise in reducing obesity and cardiovascular disease (CVD).	BMI = body mass divided by height squared. A BMI greater than 30 is used to indicate obesity. Obesity is linked to high fat diets and a decrease in physical activity. The energy intake in the diet should limit fats and free sugars, as fats have a high calorific value per gram and free sugars require no metabolic energy to be expended in their digestion. Exercise increases energy expenditure and preserves lean tissue. Exercise can help to reduce risk factors for CVD by keeping weight under control, minimising stress, reducing hypertension and improving blood lipid profiles.	Formerly key area 2.8 (b). Minor rewording for clarification. Clarification of required depth of knowledge. Body density measurements removed.

Key areas	Depth of knowledge required	Changes to content
Neurobiology and immunology		Neurobiology and Communication and Immunology and Public Health now combined.
1 Divisions of the nervous system and neural pathways (a) Structure of the central nervous system (CNS) and the peripheral nervous system (PNS). The somatic nervous system contains sensory and motor neurons. The autonomic nervous system (ANS) consists of the sympathetic and parasympathetic systems. The antagonistic actions of the sympathetic and parasympathetic systems on heart rate, breathing rate, peristalsis and intestinal secretions.	The CNS consists of the brain and the spinal cord. The PNS consists of the somatic nervous system (SNS) and the autonomic nervous system (ANS). Sensory neurons take impulses from sense organs to the CNS. Motor neurons take impulses from the CNS to muscles and glands. The sympathetic system speeds up heart rate and breathing rate while slowing down peristalsis and production of intestinal secretions. The parasympathetic system changes these in the opposite way.	New key area heading. Former key areas 3.1 (a) and 3.1 (b) combined. Reworded for clarification. Clarification of required depth of knowledge. Digestive processes now referred to as intestinal secretions.
(b) Structure and function of converging, diverging and reverberating neural pathways.	In a converging neural pathway, impulses from several neurons travel to one neuron. This increases the sensitivity to excitatory or inhibitory signals. In a diverging neural pathway, impulses from one neuron travel to several neurons so affecting more than one destination at the same time. In a reverberating pathway, neurons later in the pathway link with earlier neurons, sending the impulse back through the pathway. This allows repeated stimulation of the pathway.	Formerly part of key area 3.3 (c). Clarification of required depth of knowledge. Plasticity of response removed.

Key areas	Depth of knowledge required	Changes to content
		Former key area 3.1 (c) removed.
		Former key area 3.1 (d) removed.
2 The cerebral cortex (a) The cerebral cortex is the centre of conscious thought. It also recalls memories and alters behaviour in the light of experience. There is localisation of brain functions in the cerebral cortex. It contains sensory areas, motor areas and association areas. There are association areas involved in language processing, personality, imagination and intelligence.	There is no requirement to know the locations of these areas in the brain.	New key area heading. Former key area 3.1 (e) and part of key area 3.1 (f) combined. Reworded for clarification. Clarification of required depth of knowledge. No change to content.
(b) Information from one side of the body is processed in the opposite side of the cerebrum. Transfer of information between the cerebral hemispheres occurs through the corpus callosum.	The left cerebral hemisphere deals with information from the right visual field and controls the right side of the body and vice versa.	Formerly part of key area 3.1 (f). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
		Former key area 3.2 (a) (i), (ii) and (iii) removed.
3 Memory (a) Memory involves encoding, storage and retrieval of information. All information entering the brain passes through sensory memory and enters short-term memory (STM). Information is then either transferred to long-term memory (LTM) or is discarded.	Memories include past experiences, knowledge and thoughts.	New key area heading. Formerly part of key area 3.2. Formerly key area 3.2 (b). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.

Key areas	Depth of knowledge required	Changes to content
(b) Sensory memory retains all the visual and auditory input received for a few seconds.	Only selected images and sounds are encoded into short-term memory.	Formerly key area 3.2 (b) (i). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
(c) Short-term memory (STM). STM has a limited capacity and holds information for a short time. The capacity of STM can be improved by 'chunking'. STM can also process data, to a limited extent, as well as store it. This 'working memory model' explains why the STM can perform simple cognitive tasks.	Memory span, the serial position effect, maintaining items by rehearsal and loss of items by displacement and decay.	Formerly key area 3.2 (b) (ii). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
(d) Long-term memory (LTM). LTM has an unlimited capacity and holds information for a long time. The transfer of information from STM to LTM by rehearsal, organisation and elaboration. Retrieval is aided by the use of contextual cues.	Rehearsal is regarded as a shallow form of encoding information into LTM. Elaboration is regarded as a deeper form of encoding which leads to improved information retention. Contextual cues relate to the time and place when the information was initially encoded into LTM.	Formerly key area 3.2 (b) (iii). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
		Former key area 3.2 (b) (iv) removed.

Key areas	Depth of knowledge required	Changes to content
4 The cells of the nervous system and neurotransmitters at synapses (a) Structure and function of neurons — dendrites, cell body and axons.		Formerly key area 3.3. Formerly key area 3.3 (a)
Structure and function of myelin sheath.	Axons are surrounded by a myelin sheath which insulates the axon and increases the speed of impulse conduction.	Reworded for clarification. Clarification of required depth of knowledge.
Myelination continues from birth to adolescence.	Responses to stimuli in the first two years of life are not as rapid or co-ordinated as those of an older child or adult.	
Certain diseases destroy the myelin sheath causing a loss of co-ordination.	No requirement to know names of diseases.	
Glial cells produce the myelin sheath and support neurons.		Reference to glial cells maintaining the homeostatic environment and removing debris removed.
(b) Neurotransmitters at synapses.		Formerly key area 3.3 (b).
Chemical transmission at the synapse by neurotransmitters — vesicles, synaptic cleft and receptors.	Neurons connect with other neurons or muscle fibres at a synaptic cleft. Neurotransmitters relay impulses across the synaptic cleft. Neurotransmitters are stored in vesicles in the axon endings of the presynaptic neuron. They are released into the cleft on arrival of an impulse. They diffuse across the cleft and bind to receptors on the membrane of the postsynaptic neuron.	Clarification of required depth of knowledge. No change to content.

Key areas	Depth of knowledge required	Changes to content
The need for removal of neurotransmitters by enzymes or reuptake to prevent continuous stimulation of postsynaptic neurons. Receptors determine whether the signal is excitatory or inhibitory. Synapses can filter out weak stimuli arising from insufficient secretion of neurotransmitters. Summation of a series of weak stimuli can release enough neurotransmitter to trigger an impulse.	A minimum number of neurotransmitter molecules must attach to receptors in order to reach the threshold on the postsynaptic membrane to transmit the impulse. Convergent neural pathways can release enough neurotransmitter molecules to reach threshold and trigger an impulse.	
		Former key area 3.3 (c) moved to key area 3.1 (b).
(c) Neurotransmitter effects on mood and behaviour. The functions of endorphins. Endorphin production increases in response to severe injury, prolonged and continuous exercise, stress and certain foods. The function of dopamine.	Endorphins are neurotransmitters that stimulate neurons involved in reducing the intensity of pain. Increased levels of endorphins are also linked to the feelings of pleasure obtained from activities such as eating, sex and prolonged exercise. Dopamine is a neurotransmitter that induces feelings of pleasure and reinforces particular behaviour by activating the reward pathway in the brain. The reward pathway involves neurons which secrete or respond to dopamine. The reward pathway is activated when an individual engages in a behaviour that is beneficial to them, eg eating when hungry.	Formerly part of key area 3.3 (d). Reworded for clarification. Clarification of required depth of knowledge. No change to content.

Key areas	Depth of knowledge required	Changes to content
(d) Neurotransmitter-related disorders and their treatment. Many drugs used to treat neurotransmitter-related disorders are agonists or antagonists. Other drugs act by inhibiting the enzymes that degrade neurotransmitters or by inhibiting reuptake of the neurotransmitter at the synapse causing an enhanced effect.	Agonists are chemicals that bind to and stimulate specific receptors mimicking the action of a neurotransmitter at a synapse. Antagonists are chemicals that bind to specific receptors blocking the action of a neurotransmitter at a synapse.	Formerly part of key area 3.3 (d). Minor rewording for clarification. Clarification of required depth of knowledge provided. No change to content.
(e) Mode of action of recreational drugs. Recreational drugs can also act as agonists or antagonists. Recreational drugs affect neurotransmission at synapses in the brain altering an individual's mood, cognition, perception and behaviour. Many recreational drugs affect neurotransmission in the reward pathway of the brain. Drug addiction is caused by repeated use of drugs that act as antagonists.	Antagonists block specific receptors causing the nervous system to increase both the number and sensitivity of these receptors. This sensitisation leads to addiction where the individual craves more of the drug.	Formerly key area 3.3 (e). Reworded for clarification. Clarification of required depth of knowledge provided. No change to content.

Key areas	Depth of knowledge required	Changes to content
Drug tolerance is caused by repeated use of drugs that act as agonists.	Agonists stimulate specific receptors causing the nervous system to decrease both the number and sensitivity of these receptors. This desensitisation leads to drug tolerance where the individual must take more of the drug to get an effect.	
		All of former key area 3.4 removed.
5 Non-specific body defences (a) Physical and chemical defences. Epithelial cells form a physical barrier. Chemical secretions are produced against invading pathogens.	 Closely-packed epithelial cells are found in the skin and inner linings of the digestive and respiratory systems. Secretions include tears, saliva, mucus and stomach acid. A pathogen is a bacterium, virus or other organism that can cause disease.	New key area heading. Formerly key area 4.1. Formerly key area 4.1 (a). Minor rewording for clarification. Clarification of required depth of knowledge. No change to content.
(b) The Inflammatory response.	Histamine is released by mast cells causing vasodilation and increased capillary permeability. The increased blood flow leads to an accumulation of phagocytes and clotting elements at the site of infection.	Formerly key area 4.1 (b). Reworded for clarification. Clarification of required depth of knowledge. The secretion of cytokines and delivery of antimicrobial proteins removed.

Key areas	Depth of knowledge required	Changes to content
(c) Phagocytes. Phagocytes recognise pathogens and destroy them by phagocytosis. Phagocytes release cytokines which attract more phagocytes to the site of infection.	Phagocytosis involves the engulfing of pathogens and their destruction by digestive enzymes contained in lysosomes. Cytokines are protein molecules that act as a signal to specific white blood cells causing them to accumulate at the site of infection.	Former key area 4.1 (c) and part of key area 4.2 (a) combined. Reworded for clarification. Clarification of required depth of knowledge. Natural killer cells and apoptosis removed. Recognition of surface antigen molecules removed. General idea of immune surveillance removed.
6 Specific cellular defences against pathogens (a) Lymphocytes. Lymphocytes are the white blood cells involved in the specific immune response. Lymphocytes respond to specific antigens on invading pathogens. Antigens are molecules, often proteins located on the surface of cells that trigger a specific immune response. There are two types of lymphocytes — B lymphocytes and T lymphocytes.	Lymphocytes have a single type of membrane receptor which is specific for one antigen. Antigen binding leads to repeated lymphocyte division resulting in the formation of a clonal population of identical lymphocytes.	New key area heading. Formerly key area 4.2. Former key area 4.2 (b) and 4.2 (c) combined. Reworded for clarification. Clarification of required depth of knowledge.

Key areas	Depth of knowledge required	Changes to content
B lymphocytes produce antibodies against antigens and this leads to the destruction of the pathogen. B lymphocytes can respond to antigens on substances that are harmless to the body, eg pollen. This hypersensitive response is called an allergic reaction. T lymphocytes destroy infected body cells by recognising antigens of the pathogen on the cell membrane and inducing apoptosis. Apoptosis is programmed cell death. T lymphocytes can normally distinguish between self-antigens on the body's own cells and non-self-antigens on infected cells. Failure of the regulation of the immune system leads to T lymphocytes responding to self-antigens. This causes autoimmune diseases.	Antibodies are Y-shaped proteins that have receptor binding sites specific to a particular antigen on a pathogen. Antibodies become bound to antigens, inactivating the pathogen. The resulting antigen-antibody complex can then be destroyed by phagocytosis. T lymphocytes attach on to infected cells and release proteins. These proteins diffuse into the infected cells causing production of self-destructive enzymes which cause cell death. The remains of the cell are then removed by phagocytosis. In autoimmunity, the T lymphocytes attack the body's own cells. This causes autoimmune diseases such as type1 diabetes and rheumatoid arthritis.	Reference to B lymphocyte clones removed. Role of B lymphocytes in cell lysis removed. The secretion and effect of cytokines released by T lymphocytes removed.
(b) Some of the cloned B and T lymphocytes survive long-term as memory cells. When a secondary exposure to the same antigen occurs, these memory cells rapidly give rise to a new clone of specific lymphocytes. These destroy the invading pathogens before the individual shows symptoms.	During the secondary response, antibody production is greater and more rapid than during the primary response.	Former key area 4.2 (d) and part of key area 4.4 (b) combined. Reworded for clarification. Clarification of required depth of knowledge.

Key areas	Depth of knowledge required	Changes to content
The human immunodeficiency virus (HIV) attacks and destroys T lymphocytes. HIV causes depletion of T lymphocytes which leads to the development of AIDS (acquired immune deficiency syndrome).	Individuals with AIDS have a weakened immune system and so are more vulnerable to opportunistic infections.	Section on tuberculosis removed.
		All of former key area 4.3 removed.
7 Immunisation (a) Vaccination. Immunity can be developed by vaccination using antigens from infectious pathogens, so creating memory cells. Antigens are usually mixed with an adjuvant when producing the vaccine.	The antigens used in vaccines can be inactivated pathogen toxins, dead pathogens, parts of pathogens and weakened pathogens. An adjuvant is a substance which makes the vaccine more effective, so enhancing the immune response.	New key area heading. Formerly key area 4.4. Formerly part of key area 4.4 (a). Reworded for clarification. Clarification of required depth of knowledge. Clinical trials moved to key area 3.8.
(b) Herd immunity. Herd immunity occurs when a large percentage of a population is immunised. Establishing herd immunity is important in reducing the spread of diseases. Non-immune individuals are protected as there is a lower probability they will come into contact with infected individuals. The herd immunity threshold depends on the type of disease, the effectiveness of the vaccine and the density of the population.		Formerly part of key area 4.4 (a). Reworded for clarification. No change to content.

Key areas	Depth of knowledge required	Changes to content
Mass vaccination programmes are designed to establish herd immunity to a disease. Difficulties can arise when widespread vaccination is not possible due to poverty in the developing world, or when vaccines are rejected by a percentage of the population in the developed world.		
(c) Antigenic variation. Some pathogens can change their antigens. This means that memory cells are not effective against them. Role and impact of antigenic variation in influenza.	Antigenic variation occurs in the influenza virus explaining why it remains a major public health problem and why individuals who are at risk require to be vaccinated every year.	Formerly part of key area 4.4 (b). Evolution of mechanisms that evade the specific immune system removed. Minor rewording for clarification. Clarification of required depth of knowledge provided. Reference to malaria and *trypanosomiasis* removed.
8 Clinical trials of vaccines and drugs Vaccines and drugs are subjected to clinical trials to establish their safety and effectiveness before being licensed for use. The design of clinical trials to test vaccines and drugs involves randomised, double-blind and placebo-controlled protocols.	Subjects in clinical trials are divided into groups in a randomised way to reduce bias in the distribution of characteristics such as age and gender. In a double-blind trial neither the subjects nor the researchers know which group subjects are in to prevent biased	New key area heading. Formerly part of key area 4.4 (a). Reworded for clarification. Clarification of required depth of knowledge. No change to content.

Key areas	Depth of knowledge required	Changes to content
	interpretation of the results. One group of subjects receives the vaccine or drug while the second group receives a placebo-control to ensure valid comparisons. At the end of the trial, results from the two groups, which must be of a suitable size to reduce the magnitude of experimental error, are compared to determine whether there are any statistically significant differences between the groups.	
The importance of group size in reducing experimental error and establishing statistical significance.		