acellar  without cells; an acellular vaccine contains only parts of an infectious agent, not whole cells

active immunity  conferred when a disease or an immunization triggers production of an antibody or antitoxin (also “active immunization”)

acute (see adverse reaction)

adjuvant  a nonantigenic substance used in a vaccine to further stimulate the immune response so that less of the actual vaccine is required

adult immunizations  vaccines and boosters given to people older than 18 (commonly tetanus boosters, flu vaccines, and pneumonia vaccines)

adventitious agents  viruses and toxins — often infectious agents — that can accidentally contaminate a cell line

adverse reaction  undesirable effect of a drug, vaccine, or medical device; it can be as mild as a short-term injection-site irritation or as serious as a life-threatening acute onset of anaphylaxis; also referred to as adverse event

agammaglobulinemia  a rare, inherited X chromosome–linked (recessive) disorder that affects only males, causing the body to produce little (if any) gamma globulin (IgG) and other immunoglobulins; affected individuals develop repeated infections such as sinusitis, conjunctivitis, pneumonia, bronchitis, skin infections, and chronic diarrhea

agar  a colloidal substance (gel) extracted from certain red algae and used in tissue culture, supplemented with nutrients as required

agent  a microorganism or chemical substance, the presence or absence of which triggers a particular disease or infection

alum  common reference to potassium aluminum sulfate dodecahydrate, a crystalline compound used in water purification, leather tanning, as an astringent, and in baking powder; it occurs in nature as the mineral kalunite; in medicine it is used to stop bleeding

ampule  an airtight (sealed), sterile glass vessel containing a single drug dose

anaphylactic shock, anaphylaxis  an immediate, severe, potentially life-threatening “shock” reaction to an allergen (drug substance, food, or insect sting) resulting in breathing difficulty, a drop in blood pressure, and/or unconsciousness

antibiotic  a drug that fights a bacterial infection

antibodies (Abs)  infection-fighting proteins that the body produces to destroy foreign microorganisms or toxins (antigens); also known as immunoglobulins

antibody-mediated immunity (humoral immunity)  immunity triggered by antibodies in blood and lymphoid tissue

antigen (also immunogen)  a foreign substance in the body (a bacterium, virus, or protein, for example) that can cause disease — and whose presence triggers an immune response (the formation of antibodies)

antigenicity  the relative ability of a substance to function as an antigen
antidiotypic antibodies 
monoclonal antibodies that induce (mimic) an immune response to a similar or identical antigen (such as is present on a tumor, for example, in development of a cancer vaccine)

antimicrobial agents substances such as antibacterial, antiviral, antifungal, and antiparasitic drugs that kill disease-causing organisms

antisera serum containing antibodies (developed through immunization or infection); monovalent antisera are specific for one antigen, and polyvalent antisera apply to more than one

applied epidemiology the study of the frequency and distribution of disease in human populations as applied to public health practices

arm in clinical trials, one group of participants (an “arm” of the trial) receives one treatment (drug) while another arm receives a different treatment (placebo)

asymptomatic showing no signs of a disease or infection

attack rate the measure of disease incidence observed in a small population sample over a short time — during an epidemic, for example

attenuated vaccines a disease-causing virus is weakened (attenuated) by chemicals, aging, or nutrient deprivation to trigger a strong immune response without being able to cause the disease itself

autism a disorder more common in boys than girls, with behavior ranging from mild to severe, that adversely affects the brain’s normal development of social and communication skills and can include impaired verbal and nonverbal communication and restricted and repetitive behavior patterns

autologous derived from the same person; people facing surgery can bank their own blood for their use as an autologous donation; or a person might receive an autologous skin graft from another part of his or her body

bacterium (plural, bacteria) a single-celled, microscopic organism that reproduces by cell division, usually has a cell wall, and has no distinct cellular nucleus; some bacteria cause disease, whereas others are beneficial (aiding in digestion, for example)

big pharma the top tier of pharmaceutical companies worldwide in terms of revenue and market influence — often listed in the form of “top 10” lists, and for the most part concerned with development and production of small-molecules and/or synthetic drugs, both prescription and over-the-counter preparations

biotechnology industrial applications of genetically engineered organisms

bivalent vaccine a vaccine that contains two antigens

blood meal what a mosquito removes from its host

booster (injection) a subsequent vaccine dose given to enhance the immune response to the original vaccine antigens

bronchospasm a narrowing of the bronchial passages — one type of severe allergic reaction

broth (fermentation/cell culture) the cells, nutrients, waste, and other components that make up the contents of a microbial bioreactor

cancer vaccine a vaccine that would stimulate the immune system to recognize and kill cancer cells

carcinoma cancer

CD, CD4+ lymphocyte, and CD8+ lymphocyte certain cell-surface molecules are used to identify the maturity of immune cells based on their cluster of differentiation (CD); immune cells with the CD8 marker function as helper T cells to stimulate immune responses; cells with the CD8 marker may act as suppressor T cells that “turn off” antibody production after an antigen has been destroyed

chromatography a technique used to separate molecules based on how they bind to various solids, liquids, or gases

coccus (plural cocci) a spherical bacterium

cohort a group of people defined according to a common experience (such as birth year) or exposure, such as to a disease — and who, on that basis, may be chosen for/monitored as part of a clinical study

cold chain a series of storage and transport links (including refrigerated trucks and cold boxes) designed to keep a vaccine at the correct temperature while it travels to its destination

combination vaccine two or more vaccines administered in a single dose (MMR and DTP vaccines, for example)

community immunity (also herd immunity) if a large percentage of people in a community (or animals in a population) are vaccinated against a particular disease, that disease has less chance to occur and to therefore spread to those not directly immunized — so the entire population is protected

component vaccine (see acellular) a vaccine that contains only some components of an infectious organism to minimize the risk or occurrence of adverse reactions; the acellular pertussis vaccine is one example
congenital a condition present at birth, not generally referring to inherited/genetic disorders

conjugate vaccine a polysaccharide antigen (from, for example, tetanus or diphtheria) chemically joined with a recombinant protein for increased vaccine immunogenicity; conjugate vaccines in the childhood immunization program are Hib and MenC

cowpox (Variolae vaccinae) a disease of cattle, not usually lethal, that causes pus-filled blisters similar to those seen in smallpox

cytotoxic T lymphocyte (CTL) also known as killer T cells, CTLs are immune system cells that can destroy infected cells and cancer cells

dendritic cells the most immune-stimulating cells in the human body, occurring naturally in tissues that contact the exterior environment: in the skin and the lining of nose, lungs, stomach, and intestines; they get their name from their long tentacle-like arms, called dendrites, and form from circulating monocytes; they function as antigen-presenting cells and attract invading viruses and bacteria, then cut those proteins into short, linear peptide pieces (see epitope), and carry the fragments on their surfaces (enmeshed in their tentacles) through the blood stream to lymph nodes to activate B cells, helper T cells, and CTLs; only dendritic cells can activate a helper T cell that has never before encountered a particular antigen before

DNA vaccine (nucleic acid vaccine) injection of a gene that codes for a specific antigen, enabling the recipient to produce that antigen directly to achieve the desired immune response

efficacy proven ability of a drug or vaccine to produce a desired clinical effect at the optimal dose

ELISA (see enzyme-linked immunosorbent assay)

endemic the continual presence of a disease in a population

enzyme-linked immunosorbent assay (ELISA) in diagnostics, a blood test to measure the concentration of antibodies to a specific antigen; an experimental technique that uses enzymes to detect the presence of specific proteins

epidemic occurrence of a disease within a specific area or region in excess of its normal level (see outbreak and pandemic)

epidemiology the study of the frequency and distribution of disease in human populations

epitope functions as an antigenic determinant: a short, linear peptide sequence cut from a larger protein antigen by an antigen-presenting cell (see dendrite) and carried to the lymph node to trigger a specific immune response

expression system in genetic engineering, the cells (host organism) into which a gene is inserted to manufacture desired proteins; the gene is combined with a genetic vector (such as a virus or circular DNA molecule called a plasmid) to provide the genetic context in which it will function in the cell; that is, the gene will be expressed as the protein of interest

flagellum (plural, flagella) a propulsive structure used by some single-celled organisms to move through liquid; bacterial and archaeal flagella are helical filaments that rotate like a screw; the eukaryotic flagella (as on sperm cells) are whip-like structures

formalin generic term for a solution of formaldehyde gas in water, commercially available primarily in the form of an aqueous (37–52% wt) solution and in solid form as paraformaldehyde and used as an antiseptic and preservative

functional antibody an antibody that binds to an antigen for an effect

fungus (plural fungi) occurring as single-celled forms such as yeast and complex forms such as mushrooms, fungi can cause infections from mild skin infections such as ringworm and athlete’s foot to life-threatening conditions such as cryptococcal meningitis, histoplasmosis, and clastomycosis

genetic engineering manipulating the genetic structure of an organism through technological means rather than through traditional breeding or simple cell culture to produce a therapeutic or agricultural product

Spermatazoa use their flagella for locomotion. PhotoDisc (WWW.PHOTODISC.COM)

A eukaryotic organism’s genome is carried in its chromosomes. PhotoDisc (WWW.PHOTODISC.COM)

genome an organism’s complete set of genetic material

glycosylation a posttranslational modification in which one or more carbohydrate molecules are added onto a protein

hapten small parts of antigens that react specifically with an antibody but cannot stimulate antibody production on their own

Heaf test a commonly used tuberculosis test in which tuberculin is injected intradermally with a multiple puncture apparatus; a positive reaction indicates the presence of T-cell reactivity to mycobacterial products.

helper T cell the chief regulatory cell of the immune response, responsible for many of the immune system functions
hemoglobin the part of a red blood cell that carries oxygen

herd immunity (see community immunity)

heterologous referring to certain cells and antisera derived from a different individual or species, one immunologically related but not identical (a heterologous skin graft, for example, would not come directly from its own recipient)

Hib disease (Haemophilus influenzae type b) until recently, the most common cause of death from bacterial meningitis in children, and also the cause of blood infections, pneumonia, epiglottis, and otitis media

host cell a cell whose metabolism is used by a virus for growth and reproduction or into which a plasmid is introduced in recombinant DNA experiments; in bioprocessing, the cells engineered and cultured to express a protein of interest are the expression system host cells

host factor the intrinsic factor such as age, race, sex, or behavior that influences a person's exposure, susceptibility, or response to a causative agent

HVAC the heating, ventilation, and air conditioning system of a building

hypnozoite the form of the malaria parasite that remains in the liver and causes relapses

hypogammaglobulinemia a condition characterized by very low levels of all types of immunoglobulins

immune complex the result of a reaction between an antigen and a specific antibody

immune response the reaction of the immune system to foreign organisms

immune serum a serum obtained from human or animal sources and containing naturally or artificially produced antibodies to a given antigen

immunity measured by the presence of antibodies in the blood, a natural or acquired resistance to a specific disease, whether partial or complete, specific or nonspecific, lasting or temporary

immunodeficiency (also immunosuppression) condition in which the normal immune response is weakened or diminished from the effects of disease or drugs

immunogen (see antigen)

immunogenicity the relative ability of an antigen or vaccine to elicit an immune response

immunoglobulin (IG) when administered, an antibody that confers short-term immunity; immune gamma globulin (IGG) provides passive protection against viral infections such as hepatitis A, measles, rubella, and varicella; immune globulin (human) (IGH) is used to prevent hepatitis B

immunomodulator a chemical agent that modifies the immune response or the functioning of the immune system

immunosupression (see immunosuppression)

immunotherapy (also called biological therapy) most often referred to as a process in which allergic patients receive small, weekly doses to desensitize them to allergic substances (by developing a protective antibody, immunoglobulin G, to block the allergic reaction); in vaccine research, it refers to efforts to harness the body's ability to develop immune defenses against cancerous cells.

inclusion criteria characteristics that must be met by all who participate in a clinical trial

incubation period a period following exposure to an infectious agent during which inapparent pathological changes culminate in the onset of disease

IND (see investigational new drug application)

infectious agents organisms (such as bacteria, viruses, and fungi) that cause disease

inflammation heat, pain, redness, and/or swelling; reactions to the release of body chemicals at a site of tissue damage; physical injury; bacterial, viral, fungal, or parasitic infection; or an allergic reaction

inoculation introducing material (a vaccine, for example) into the body's tissues; also introducing cells into a culture medium

international transportation of disease transmission of a disease from one country to another through an infected person, insect, or increasing ability of a pathogen to avoid the immune system

intracellular proteins the most ancient proteins present in all eukaryotes (multicellular organisms) are intracellular proteins, which are involved in cellular functions such as genetic transcription, DNA repair, and membrane transport

investigational new drug (IND) application a form submitted by a company as a request for FDA's permission to expose healthy human volunteers to an experimental drug; must be filed for each clinical trial performed, phases 1–3

joint committee on vaccination and immunization (JCVI) nondepartmental public body and statutory expert standing advisory committee that advises the secretaries of state for health in Scotland, Wales, and Northern Ireland on matters relating to communicable diseases that are potentially preventable through immunization

liposomes microscopical, fluid-filled pouches with walls made of layers of phospholipids identical to those that make up cell membranes; used to deliver certain vaccines, enzymes, or drugs (e.g., insulin and some cancer drugs) to the body; used in the delivery of some cancer drugs to shield healthy
cells from the drugs’ toxicity and prevent their concentration in vulnerable tissues, lessening or eliminating common side effects; also used experimentally as a method of carrying normal genes into cells to replace defective, disease-causing genes

**live-vector vaccine** a vaccine that stimulates an immune response by using a non–disease-causing bacterium or virus to transport foreign genes into the body

**long-term memory** the immune-system’s ability to remember and defend against foreign proteins when challenged; certain vaccines are better at inducing long-term memory than others (the tetanus vaccine, for example, as compared with influenza vaccines)

**lyophilization** freeze-drying

**master cell bank** a culture of fully characterized cells processed together to ensure uniformity and stability and used to prepare the working cell banks for production

**microencapsulation** the process of trapping cells inside a thin, protective, often biodegradable membrane to help anchor them and protect them against harsh conditions

**monoclonal antibody (MAb)** a highly specific, purified antibody that recognizes only a single epitope

**monovalent vaccine** a vaccine that recognizes only one antigen

**morbidity** exhibiting illness or disease; also the percentage of illness or disease in a population

**mortality** death; also referring to the percentage of deaths in a population

**multidrug resistance** the ability of a pathogen to withstand a number of antimicrobial drugs — such as those that might have fought that pathogen before

**mutation** a change (usually rare and random) in the base sequence of a DNA molecule

**outbreak** the spread of a disease over a short period in a limited geographical area

**pandemic** the spread of a disease (an epidemic) over a very large geographical area

**parenteral** a medicine that is administered intravenously or by injection; most vaccines can be administered subcutaneously (to the fatty layer immediately below the skin) or intramuscularly — but not intravenously

**perfusion** a fermentation process used for antibody production in which high concentrations of mammalian cells inside a chamber receive fresh growth medium continually as waste products are removed

**pharmacokinetics** study of ADME processes (adsorption, distribution, metabolism, and excretion)
placebo: an inactive substance (or another vaccine that will elicit different immune responses from the one being tested) administered to some clinical trial participants to provide a basis for comparison of effects

plasmid: circulating, self-replicating DNA found in the cytoplasm of the cells of bacteria and some yeasts and used as vectors for introducing foreign genes into recipient cells

plasmodium spp: malaria

polyvalent vaccine: a vaccine that contains several antigens

pre-erythrocytic: before entering red blood cells

prevalence: the measure of people in a population affected by a disease or condition at a particular time

prime-boost (also heterologous boosting, priming): in cases when the immune response from a single dose of a vaccine is insufficient to provide effective protection, the same antigen can be administered in two different vectors, successively: The first vector (a live-vector vaccine, for example) “primes” the immune response with the antigen, and reexposure in the second vector (such as a recombinant subunit vaccine) “boosts” that response; contrasts with the traditional method of homologous boosting in which two or more doses of the same vaccine are given successively

prophylaxis: prevention of a disease or condition

proteomics: the study of protein function and structure by organism

protocol: documentation that ties together all SOPs (standard operating procedures) to direct the work performed in a regulated facility: who approves what, who is allowed to sign off on materials and products, where certain files and documents are kept, and so on; also a detailed plan for a clinical trial, stating (among other things) the trial’s rationale, purpose, scope, dosages, routes of administration, length of study, and eligibility criteria

protozoa: single-celled organisms, many of which are parasitic (e.g., the malaria parasite)

quadrivalent vaccine: a vaccine that contains four antigens

randomized trial: a study in which participants are randomly assigned to one of two or more trial arms to minimize potential grouping or prevalence of certain characteristics

reassortant virus: in viruses with segmented genomes, hybrid virions containing segments from different “parent” viruses can be produced by cells infected with different strains of the virus (giving rise to new strains)

receptor: a molecule on the surface of a cell that can bind antigens, antibodies, or other cellular components

resistance (see multidrug resistance)

risk, risk factor: along with the probability that an event will occur (risk) are those factors of behavior, lifestyle, environment, or heredity associated with increasing or decreasing that probability

scale-up: the steps involved in transferring a manufacturing process or section of a process from laboratory scale to the level of commercial production

seroconversion: development of antibodies in the blood that were not there before vaccination

sparging: spraying: a sparger on a fermentor sprays air into the broth

sterilizing immunity: an immune response that is completely effective at preventing infection

strain: a genetic variant within a species

substrate (in cell culture): surface on which a cell or organism grows or is attached — such as the use of microcarriers in cell culture; most eukaryotic cell types require attachment to a substrate for survival; also called extracellular matrices; in the body they are composed mainly of proteins and provide chemical cues that affect or guide the behavior of cells

surrogate marker: an indirect measure of disease progression

suspending fluid: the substance that carries a vaccine into the body

thimerosal (also thiomersal): a mercury-based preservative used in some vaccines to prevent contamination and also used as a formulation ingredient in inactivated vaccines

This bioreactor is growing cells using small disks as a substrate.

NEW BRUNSWICK SCIENTIFIC, INC. (WWW.NBSC.COM)

malaria parasite

Mercury is an ingredient of thimerosal.

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titer: the quantity of one substance required to produce a reaction with a specific volume of another; also the number/measure of antibodies detected in blood

trivalent vaccine: a vaccine that contains three antigens
vaccine association  administering several vaccines to different sites of the body at the same time

valence  measure of the number of antigens contained in a vaccine

validation  determining the degree of validity; procedures involved in checking data or processes for correctness, compliance with standards, and conformance with requirement specifications

vector  a plasmid, virus, or other vehicle for carrying a DNA sequence into the cells of another species; also a method (such as genetically engineered viruses or bacteria) of delivering genetic material to cells

vesicle  a blister or cavity that can hold liquid

virus  a microorganism that grows and reproduces in living cells of a host (bacteria, plant, or animal); the simplest form of life, more than 200 viruses are known to produce human disease

virus-like particles (VLPs)  noninfectious analogs of pathogenic viruses; cultured cells can be infected with a live virus, causing them to express viral proteins on their surfaces; once transferred into an individual, those viral proteins elicit an immune response, resulting in soluble antibodies in serum that in turn bind to live virus and block infection; VLPs also can be created by removing genes encoding for virulence from live viruses

water for injection (WFI)  very pure water used for medical purposes

working cell bank  cells used in pharmaceutical production grown from those maintained in a master cell bank so that their stability and uniformity are well characterized