

University of Delaware
Foodborne Illness Outbreak Investigation
Glossary

Accuracy: Test accuracy is the proportion of all tests, both positive and negative, that are correct. It is often used to express the "overall performance" of a diagnostic test.

Agent: a factor, such as a microorganism, chemical substance, or form of radiation, whose presence, excessive presence, or (in deficiency diseases) relative absence is essential for the occurrence of a disease. A disease may have a single agent, a number of independent alternative agents (at least one of which must be present), or a complex of two or more factors whose combined presence is essential for the development of the disease.

Apparent prevalence: The prevalence of disease estimated on the basis of diagnostic tests (compare with real prevalence).

Assay: procedure to analyze something

Asymptomatic: without symptoms or producing no symptoms.

Attack rate: The proportion of a defined population affected during a particular outbreak. It is equal to the total number of cases during the outbreak period divided by the number of individuals initially exposed, i.e., those present at the beginning at the outbreak.

Attributable risk (risk difference): The additional incidence of disease attributable to a risk factor itself. It is calculated by subtracting incidence among those not exposed to a risk factor from incidence among exposed individuals.

Bacteria: single-celled, prokaryotic microorganism

Bias: A mental leaning or inclination. Not leaving the mind indifferent. Syn. - tendency, inclination, propensity, disposition, bent, prejudice, warp.

Carrier: A person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source of infection. The carrier state may occur in an individual with an infection that is inapparent throughout its course (known as healthy or asymptomatic carrier) or during the incubation period, convalescence, and postconvalescence of an individual with a clinically recognizable disease (known as incubatory carrier or convalescent carrier). The carrier state may be of short or long duration (temporary or transient carrier or chronic carrier).

Carrier state: A state of infection in which an infected host can communicate the infection in the absence of manifest disease.

Case: A particular instance of a disease, health disorder, or condition under investigation. A variety of criteria may be used to identify cases, e.g., individual physicians' diagnoses, registries and notifications, abstracts of clinical records, surveys of the general population, population screening, and reporting of defects such as in a dental record. The epidemiologic definition of a case is not necessarily the same as the ordinary clinical definition.

Case control (retrospective) study: Subjects are followed backward in time, from effects to possible causes: cases and noncases are not necessarily members of same population group.

Case definition: The combination of history, physical or laboratory findings that are characteristic of a particular disease syndrome. It should include all true cases of the disease and exclude similar, but unrelated conditions. The case definition is the starting point for determining risk, prognosis or the effectiveness of therapeutic regimens.

Case fatality rate: Number of deaths attributable to a disease during an outbreak divided by the number of cases of that disease during the outbreak period.

Case finding: the process of identifying all possible cases; this typically uses a broad case definition (see above) and occurs early in the investigation. Later in the investigation, case finding might be performed to assess the extent of the outbreak.

Case report: Detailed presentation of a single case or a handful of cases (<10); may be either cross-sectional or longitudinal.

Case series: Cross-sectional study with no defined population and no comparison group.

Case-control study: the observational epidemiologic study of a person or persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and nondiseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups. In short, the history of exposure to suspected risk factor is compared between "case patients" and "controls," persons who resemble the case patients in such respects as age and sex but do not have the disease or condition of interest.

Case-finding: The use of screening tests to search for disease among a clinician's own patients, who are consulting for unrelated symptoms. Typically, every animal is sampled and the objective is to identify the affected individual.

CDC: United States Centers for Disease Control and Prevention

Chain of custody: a record which establishes the complete chronological disposition of an entity of concern, e.g. a sample or a document.

Clinical course of disease: The progression of disease once it has come under medical care (compare with natural history of disease).

Clinical epidemiology: Clinical epidemiology focuses on the sorts of questions asked in the practice of medicine. Consequently, the findings have a direct application in medical decision making. Studies may be observational or experimental.

Cluster: aggregation of relatively uncommon events or diseases in space and/or time in amounts that are believed or perceived to be greater than could be expected by chance. Putative disease clusters are often perceived to exist on the basis of anecdotal evidence, and much effort may be expended by epidemiologists and biostatisticians in demonstrating whether a true cluster exists. With modern molecular laboratory techniques, clusters of infections with "identical" organisms are being uncovered; the significance of these clusters is currently a topic of discussion.

Coefficient of determination (r^2): The square of the correlation coefficient. A measure of closeness of fit of the data to the linear regression line. The value for r^2 expresses the amount of variation in the data that are accounted for by the linear relationship between two variables and may take any value between 0 and 1. As the amount of variability, or "scatter," around the fitted regression line increases, the value of r^2 decreases. An r^2 value of 1 means that all values fall on the regression line.

Cohort: A group of individuals who have something in common when they are first assembled, and who are then observed for a period of time to see what happens to them (see survival cohort).

Cohort (prospective) study: Subjects are followed forward in time, from possible causes to effects. In a concurrent cohort study the cohort is assembled in the present and followed into the future. In a historical cohort study the cohort is identified from past records and followed forward from that time up to the present.

Commercial confidential: trade secrets that are protected by law from public disclosure (e.g., monitoring records, customer lists, and traceback information). Unlawful release of this information can result in legal punishment including imprisonment.

Common source outbreak: outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group. When the exposure is brief and essentially simultaneous, the resultant cases all develop within one incubation period of the disease (a "point" or "point source" outbreak).

Communicable disease: An illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal or inanimate reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector or the inanimate environment (Benenson, 1985).

Communicable period: The time or times during which an infectious agent may be transferred directly or indirectly from an infected person to another person, from an infected animal to humans or from an infected person to an animal, including invertebrate vectors (Benenson, 1985).

Compliance: The proportion of individuals (or their owners) that adhere to the prescribed treatment regimen. Thus an efficacious treatment could be ineffective due to poor compliance.

Confidence interval: The theoretical range over which there is a specified probability (usually 95%) of including the true value.

Confidence intervals (CI): the computed interval with a given probability, e.g., 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval. This is a measure of statistical significance; if a confidence interval includes the value 1.0, the study findings are said to be not statistically significant at the given level of certainty.

Confirmation: diagnosis of most diseases can be confirmed only if etiologic agents are isolated and identified from specimens obtained from ill persons.

Confirmed cases: usually cases that have met the case definition (see above) for symptoms AND in which infection is verified by laboratory test (e.g., culture)

Confirmed outbreak: clusters (see above) which are confirmed by laboratory or epidemiologic study to be caused by a common agent or to have occurred among persons who have shared a common exposure.

Confounding: 1. A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure risk brought about by the association with other factors that can influence the outcome. 2. A relationship between the effects of two or more causal factors as observed in a set of data such that it is not logically possible to separate the contribution that any single causal factor has made to an effect. 3. A situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

Confounding variable: A variable that is related to two factors of interest (e.g., disease state and degree of exposure to some agent in a case-control study; treatment assignment and outcome in a clinical trial) that falsely obscures or accentuates the relationship between the factors. (2) A baseline variable in a clinical trial that influences the outcome and that has a different distribution in the treatment groups being compared.

Congenital transmission: Transmission occurring at, and usually before, birth transovarially, via the placenta, or via the colostrum.

Contagious infection: A transmissible infection that is spread only as the result of an intimate association or contact with infected animals or their excretions or secretions.

Contaminant: an infectious agent or a chemical or physical hazard.

Contamination: the presence of an infectious, chemical, or physical agent or substances in or on water, milk, and food that has the potential to cause harm, including illness or injury.

Contamination factors: 1. Natural toxin 2. Poisonous substance intentionally added. 3. Poisonous or physical substance accidentally or incidentally added. 4. Addition of excessive quantities of ingredients that under these situations are toxic. 5. Toxic container or pipelines. 6. Raw product or ingredient contaminated by pathogens from animal or environment. 7. Ingestion of contaminated raw products. 8. Obtaining foods from polluted sources. 9. Cross-contamination from raw ingredient of animal origin. 10. Bare-hand contact by food worker. 11. Handling by an intestinal carrier of enteric pathogens. 12. Inadequate cleaning of processing or preparation equipment or utensils. 13. Storage in contaminated environment.

Contributing factors: factors that contribute to contamination and survival of the etiologic agents and perhaps also to their growth or amplification. These include 1. Factors that introduce or otherwise permit contamination, 2. Factors that allow survival of or fail to inactivate the contaminant, 3. Factors that allow proliferation of the etiologic agents.

Controls: subjects with whom comparison is made in a case-control study, randomized controlled trial, or other type of epidemiologic study. Selection of appropriate controls is crucial to the validity of epidemiologic studies and has been much discussed.

Crude death rate: Number of deaths during an outbreak/mean population during the outbreak period.

Cyclical changes: Increases or decreases in rates (such as disease incidence) developing at intervals longer than a year.

Descriptive epidemiology: Descriptive epidemiology endeavors to describe and quantify the distribution of diseases and associated factors in terms of individuals, place and time. Results are

typically expressed as rates, which require numerator (affected individuals) and denominator (population at risk) data.

Diagnostic test: Use of a test to discriminate animals that have the disease in question from those that have other diseases that compete with the disease of interest in the differential diagnosis (White, 1986). Diagnostic testing begins with diseased individuals.

Diarrhea: (specific characteristics, number within a period of time) - an abnormally frequent discharge of semisolid or fluid fecal matter from the bowel. In foodborne disease outbreaks, diarrhea is most commonly defined as 3 or more loose, watery stools in a 24-hour period. Diarrhea can also be further described by such things as the presence of blood, greasy texture, or dark color.

Dissemination: See mode of spread.

Ecological epidemiology: Ecological epidemiology focuses on understanding the important factors that affect transmission of particular disease agents. These factors are frequently referred to as the "host, agent and environment triad."

Effectiveness: A measure of how well a treatment works among those to whom it is offered (compare with efficacy).

Efficacy: The power to produce effects or intended results. A measure of how well a treatment works among those who receive it (compare with effectiveness).

Endemic disease: A disease that occurs with predictable regularity in a population unit with only relatively minor fluctuations in its frequency (see epidemic and sporadic).

Enzyme: biological catalyst

Epi curve: a graphic plotting of the distribution of cases by time of onset. Epi curves help characterize an outbreak and give clues about the source of the outbreak (e.g., common or point source, secondary spread)

Epi traceback: a preliminary investigation of product distribution. It is used by epidemiologists to help distinguish between two or more implicated products, to strengthen an association, or to develop hypotheses.

Epidemic (epizootic) disease: A disease whose frequency in a population during a given time interval is clearly in excess of its expected frequency, as during an outbreak (compare with endemic and sporadic).

Epidemiology: The study of health and disease in populations. Epidemiology involves (1) the observational study of naturally occurring versus experimentally induced disease, (2) the study of disease in the population versus the individual and (3) the detection of associations by inferential methods versus the study of pathologic mechanisms.

Etiologic agent: see agent

Etiologic epidemiology: Etiologic epidemiology is primarily concerned with establishing causal relationships in diseases of undetermined origin. Other terms that have been used to describe this activity are "medical detection" and "shoe-leather" epidemiology.

Experimental study: Epidemiologic study in which the researcher tries to alter the course of events by manipulating the conditions of the experiment. Experimental studies may evaluate the relative merits of various therapeutic, surgical or preventative measures for a particular disease syndrome (compare with observational study).

Exposure: 1. Proximity and/or contact with a source of a disease agent in such a manner that effective transmission of the agent or harmful effects of the agent may occur. 2. The amount of a factor to which a group or individual was exposed, sometimes contrasted with dose, the amount that enters or interacts with the organism. Note: Exposures may be beneficial as well as harmful; e.g., exposure to immunizing agents.

Extrinsic incubation period: The period of time between infection of a biological vector and acquisition by the vector of the ability to transmit the agent to another susceptible vertebrate host.

Extrinsic risk factors: Risk factors that are not properties of the host, i.e., agent and environment.

False-negative rate: The likelihood of a negative test result in patients known to have the disease.

False-positive rate: The likelihood of a positive test result in patients known to be free of the disease.

FDA: United States Food and Drug Administration

Firm: any individual, partnership, corporation, or association that deals in articles subject to the FD&C Act.

Food preparation review: a review done on each food or menu item that has been implicated in an outbreak. The review focuses on possible means of contamination, growth, or survival of pathogens. Food preparation reviews include a detailed step-by-step observation of the processes used in making, serving, storing, and transporting the implicated food item. Measurements such as times, temperatures, pH, size of containers/cooking vessels/cooling/storage containers, and amounts of ingredients/products must be included in a food preparation review. An example is given in the Procedures to Investigate Foodborne Illness, 5th edition, IAMFES.

Food worker: person directly involved in producing, harvesting, processing, packaging, preparing, or storing the food under investigation.

Food-specific attack rate: a comparison of the illness rate among those who ingested specific foods at an event or meal with the illness rate of those who were at the event or meal but did not ingest these items. A food-specific attack rate table is used for cohort studies when the entire group at the event is known and interviewed about illness and exposure.

FoodNet: Foodborne Disease Active Surveillance Network; a surveillance network coordinated by CDC, FDA, and FSIS/USDA among several state health departments, designed to provide more accurate estimates of the number and source of cases of foodborne illness in the United States.

Gold standard: The gold standard refers to the means by which one can determine whether a disease is truly present or not. Its function is that of a quality-control device.

HACCP: a prevention-based food safety system that identifies and monitors specific foodborne hazards--biological, chemical, or physical properties--that can adversely affect the safety of the food

product. This hazard analysis (HA) serves as the basis for establishing critical control points (CCPs), those points in the process that must be controlled to assure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to assure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan.

Herd health/preventive medicine: Herd health/preventive medicine endeavors to use epidemiologic information to design optimal disease prevention strategies. Economic considerations, expressed either as cost-effectiveness or cost-benefit, frequently determine which strategy is most effective.

Herd immunity: The proportion of animals in a population that are resistant to infection or disease.

Horizontal transmission: Transmission of an infectious agent between contemporaries, or animals of more or less the same generation (see vertical transmission).

Host: 1. A person or other living animal, including birds and arthropods, that affords subsistence or lodgment of an infectious agent under natural conditions. Some protozoa and helminthes pass successive stages in alternate hosts of different species. Hosts in which the parasite attains maturity or passes its sexual state are primary or definitive hosts; those in which the parasite is in a larval or asexual state are secondary or intermediate hosts. A transport host is a carrier in which the organism remains alive but does not undergo development. 2. In an epidemiologic context, the host may be the population or group; biological, social, and behavioral characteristics of this group that are relevant to health are called "host factors."

Hypothesis: 1. A supposition arrived at from observation or reflection that leads to refutable predictions. 2. Any conjecture cast in a form that will allow it to be tested and refuted. 3. Initial interviews with ill persons in an outbreak are often done to generate hypotheses about the cause of the outbreak and are typically more open-ended than interviews of case-patients and controls.

Immunoassay: biochemical test to measure presence or quantity of substance based on specificity of reactions between antibodies and antigens

Implicated food: Food thought to be the outbreak vehicle, i.e., food thought to have made people ill, based on laboratory results and/or epidemiologic evidence.

Incidence: The proportion of individuals that develop a condition of interest over a defined period of time. Incidence takes into account new cases only, i.e., cases that have their onset during the time period specified. It is, therefore, a measure of the risk of becoming a case over a defined time period.

Incubation period: The time interval between invasion by an infectious agent and appearance of the first sign or symptom of the disease in question.

Index case: The case that brings a group to the attention of health care personnel.

Infection: the entry and development of multiplication of an infectious agent in the body of humans or animals. Infection is not synonymous with infectious disease: the result may be inapparent or manifest. The presence of living infectious agents (e.g., pediculosis, scabies) on exterior surfaces of the body is called infestation. The presence of living infectious agents upon articles of apparel or soiled articles is not infection, but represents contamination of such articles.

Intentional contamination: a deliberate adding of a contaminant to food in quantities sufficient to cause illness. Contaminants added because of sabotage, mischievous acts, and intents to cause panic or blackmail a company fall into this category.

Intoxication (microbiological, foodborne): illness caused by toxin produced by microorganism. Examples include toxins produced by *Clostridium botulinum* and *Staphylococcus aureus*.

Intrinsic incubation period (incubation period): The period of time between infection of the vertebrate host and the appearance of clinical signs.

Intrinsic reproductive rate (basic reproductive rate): The number of secondary infections produced by one case in a totally susceptible population.

Intrinsic risk factors: Risk factors that are properties of the host.

Investigator: Epidemiology: Any person involved in determining the agent, mode of transmission and factors leading to an illness or outbreak. Regulatory: A person specially trained to collect evidence of violations of regulatory requirements. This evidence is collected for use in possible enforcement actions by the regulatory agency.

Irregular variation: Reflects random variation in disease occurrence among individuals in a population.

Latency: A state of infection in which an agent is quiescent in a host and, therefore, difficult to detect; implies a potential for activity.

Likelihood ratio: A single measure that summarizes a test's performance. The likelihood ratio for a positive result is the ratio of the likelihood of a positive result in patients with disease to the likelihood of a positive result in patients without disease (true-positive rate/false-positive rate). The likelihood ratio for a negative test result is the ratio of the likelihood of a negative result in patients with disease to the likelihood of a negative result in patients without the disease (false-negative rate/true-negative rate).

Longitudinal study: Subjects are observed over a period of time, either retrospectively (patient history and medical records) or prospectively (through follow-up).

Market withdrawal: a firm's removal or correction of a distributed product that involves a minor violation for which FDA would not initiate legal action, or which involves no violation (e.g., normal stock rotation practices).

Mass screening: The application of screening tests to large unselected populations. Identification of an affected population may then lead to case finding through testing of each animal in the herd.

Measure of association: a quantity that expresses the strength of association between variables. Commonly used measures of association are differences between means, proportions or rates, the rate ratio, the odds ratio, and correlation and regression coefficients.

Measures of effect: Measures of the association between exposure and disease. Included are relative risk, attributable risk, population attributable risk and population attributable fraction.

Microscopy: technique to view objects smaller than can be seen with the unaided eye.

Mode of spread: Refers to how a disease agent is spread from one geographic area to another. Synonymous with dissemination.

Mode of transmission: The way(s) in which an etiologic agent is transmitted from affected to susceptible individuals.

Morbidity rates: Direct measures of the commonness of disease in a population. Examples are attack rate, incidence and prevalence (see vital statistics).

Mortality rate: An incidence rate in which the numerator is the number of deaths occurring in a population over a defined period of time. The denominator is the population at risk over that time period.

Natural history of disease: The evolution of disease without medical intervention (compare with clinical course of disease).

Negative correlation: See correlation coefficient.

Nominal data: Data that can only be placed into categories, without any inherent order. For analytic purposes nominal data is treated as discrete variables.

Nonrandomized controlled clinical trial: Patients are allocated to concurrent comparison groups by means of some nonrandom process (e.g., convenience, clinical judgement, owner preference).

Notifiable : Disease or condition that must be reported by medical professionals to public health authorities. Notifiable foodborne illnesses include: Anthrax, Botulism, Brucellosis, Cholera, Enterohemorrhagic *E. coli*, Hemolytic uremic syndrome, post-diarrheal, Listeriosis, Salmonellosis (other than *S. typhi*), Shigellosis, Typhoid fever (*S. Typhi* and *S. Paratyphi*), Hepatitis A, Cryptosporidiosis, Cyclosporiasis, Giardiasis, Trichinellosis

Nucleotide: molecule consisting of sugar, phosphate group, and nitrogenous base. Nucleotides linked together in a chain form DNA and RNA.

Null hypothesis: The hypothesis, or operational assumption, that no difference exists between treatment groups. Observed difference are due to chance.

Objective data: Measurable indices such as temperature, pulse, respiration, results of parasitologic examinations, complete blood counts, radiographs, etc.

Observational study: Epidemiologic study in which the researcher is merely an observer and does not interfere with the natural course of events. Observational studies focus on such things as assessment of risk, cause or prognosis (compare with experimental study).

Odds ratio: The odds that a case is exposed divided by the odds that a control is exposed to a risk factor. The odds ratio provides a measure of risk for case control studies that is conceptually and mathematically similar to the relative risk obtained in cohort studies, e.g., the stronger the association between exposure and disease, the higher the odds ratio.

Odds ratio (OR): the ratio of two odds. The term odds is defined differently according to the situation under discussion. Using a standard 2 x 2 table, the odds ratio (cross-product ratio) is ad/bc . Case Control
Exposed a b Not Exposed c d

Outbreak: an epidemic limited to localized increases in the incidence of a disease, e.g., in a village, town, or closed institution; upsurge is sometimes used as a euphemism for outbreak.

Outbreak period: Period of time over which the first and last cases occurred in a population during an outbreak.

P value: The likelihood that an observed result could have arisen by chance alone.

Pandemic: A very large scale epidemic, usually involving several countries or continents.

Parallel testing: The performance of two or more tests on a patient or herd at the same time. The net effect of parallel testing is to ask the patient to prove that it is healthy.

Parenteral: Not through the alimentary canal, i.e., such as subcutaneous, intramuscular, intradermal, intravenous, etc.

Patency: A state of infection in which an agent can be recovered or identified from blood or tissues.

Pathogen: organism capable of causing disease (literally, causing a pathological process).

Pathogenicity: A measure of an agent's ability to induce disease (see virulence).

Pathognomonic: Specifically distinctive or characteristic of a disease or pathologic condition and rarely found in healthy individuals or those afflicted with clinically similar conditions; a sign or symptom on which a diagnosis can be made.

PCR: polymerase chain reaction – a form of molecular testing which allows the specific identification of an organism from small quantities of its DNA.

Period prevalence: Number of cases (old and new) detected over a time period/number of animals examined over the same time period.

Pesticide: any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Pests can be insects, mice and other animals, unwanted plants (weeds), fungi, or microorganisms like bacteria and viruses. Though often misunderstood to refer only to insecticides, the term pesticide also applies to herbicides, fungicides and various other substances used to control pests. Under United States law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. Common pesticides include algaecides, antifouling agents, antimicrobial agents, attractants, biocides, disinfectants and sanitizers, fungicides, fumigants, herbicides, insecticides, miticides, microbial pesticides, molluscicides, nematocides, ovicides, pheromones, repellents, rodenticides, defoliants, desiccants, insect growth regulators and plant growth regulators.

PFGE: pulsed-field gel electrophoresis – a molecular method that allows for the specific classification of pathogens by “fingerprinting” the DNA from the pathogen; this method generates visually observable patterns which can be digitized and then compared with other pathogens of the same genus and species. Pathogens with patterns characterized as “indistinguishable” may have similar sources. Two persons or items yielding indistinguishable organisms are more likely to be related (i.e., be part of the same outbreak) than if the organisms with different PFGE patterns are isolated.

Point prevalence: Number of cases (old and new) detected at a particular point in time/number of animals examined at the same point in time.

Point source epidemic: An outbreak characterised by a single peak in the epidemic curve, suggestive of a common source of exposure at a single point in time. An example is a foodborne disease outbreak. Also known as a common source epidemic.

Point source outbreak: see common source outbreak

Polymerase: enzyme catalyzes reaction for formation of a polymer, which consists of many, repeating, structural units called monomers

Population at risk: Population group in which an event could occur.

Population attributable fraction: The fraction of disease occurrence in a population that is associated with a particular risk factor. It is estimated by dividing the population attributable risk by the total incidence of disease in the population.

Population attributable risk: A measure of the excess incidence of disease in a population that is associated with the occurrence of a risk factor. It is the product of the attributable risk and the prevalence of the risk factor in a population.

Positive correlation: See correlation coefficient.

Posterior likelihood of a disease: The product of the prior likelihood and conditional likelihood of a disease. Also known as the revised likelihood of a disease.

Power of a test: The probability that a trial will find a statistically significant difference when a difference really exists. A powerful test has a higher probability of rejecting the null hypothesis when it should be rejected. Power is analogous to the sensitivity of a diagnostic test and is equal to 1 minus the probability of a beta error.

Predictive value: The probability of a disease, given the results of a test, is called the predictive value of the test. Positive predictive value is the probability of disease in an animal with a positive (abnormal) test result. Negative predictive value is the probability that an animal does not have the disease when the test result is negative (normal).

Prepatent period: The period of time between infection of the vertebrate host and detectability of an agent in secretions, excretions, blood or tissues.

Prevalence: The proportion of sampled individuals possessing a condition of interest at a given point in time. It is measured by a single examination of each individual of the group. Prevalence can be likened to a "snapshot" of the population and includes both old and new cases. It is a measure of the risk of being a case at a given moment.

Prevalence survey: Cross-sectional study of a defined population; commonly used in outbreak investigations.

Primary case: The first case(s) in a group that may serve as a source of infection.

Prior likelihood of a disease: A numerical estimate of the probability of any disease in a cohort of patients identical to the one in question. It is based in part on the combination of signs and symptoms, and in part on the prevalence of the condition in the population.

Prognosis: The prediction of the future course of disease following its onset.

Prognostic factors: Conditions that, when present in individuals already known to have disease, are associated with an outcome of the disease.

Proliferation/amplification factors: factors that allow proliferation of the etiologic agents: 1. Allowing foods to remain at room or warm-outdoor temperature for several hours. 2. Slow cooling. 3. Inadequate cold-holding temperature. 4. Preparing foods a half-day or more before serving. 5. Prolonged cold storage for several weeks. 6. Prolonged time and/or insufficient temperature during hot holding. 7. Insufficient acidification. 8. Insufficiently low water activity. 9. Inadequate thawing of frozen products. 10. Anaerobic packaging or modified atmosphere. 11. Inadequate fermentation.

Propagating epidemic: An outbreak characterised by an initial increase in disease frequency (primary cases) followed by a secondary increase with a broad peak (secondary cases). An example is an outbreak of a directly-transmissible venereal disease.

Protocol: procedure

Protozoa: unicellular, non-fungal, eukaryotic microorganisms

PulseNet: the National Molecular Subtyping Network for Foodborne Disease Surveillance; a network of laboratories throughout the United States that perform testing on foodborne pathogens using standard methods (currently PFGE) and compare results via images on a computer network.

Questionnaire: a predetermined set of questions used to collect data on (e.g.) clinical characteristics, social status, or occupational group. This term is often applied to a self-completed survey instrument, as contrasted with an interview schedule.

Randomized controlled clinical trial: Subjects are randomly allocated into treatment and control groups.

Recall : A firm's voluntary removal or correction of a marketed product(s), including its labeling and/or promotional materials, that FDA or FSIS considers to be in violation of the laws it administers, and for which the agency would initiate legal action (e.g., seizure or the full range of administrative and civil actions available to the agency). "Recall" does not include a market withdrawal or stock recovery.

Regulatory authority: Agency that regulates (permits/licenses and inspects) the substance or establishment under consideration.

Relative risk (risk ratio): The ratio of incidence in exposed individuals to incidence in nonexposed individuals. Relative risk is an index of the strength of the association between exposure and disease. If no additional risk is associated with exposure, then both incidences should be equal and the ratio would be equal to 1.

Relative Risk (RR): 1. The ratio of the risk of disease or death among those exposed to the risk among the unexposed; this usage is synonymous with risk ratio. 2. Alternatively, the ratio of the cumulative incidence rate in the exposed to the cumulative incidence rate in the unexposed, i.e., the cumulative

incidence ratio. 3. The term relative risk has also been used synonymously with odds ratio and, in some biostatistical articles, has been used for the ratio of forces of morbidity. The use of the term relative risk for several different quantities arises from the fact that for "rare" disease (e.g., most cancers) all the quantities approximate one another. For common occurrences (e.g., neonatal mortality in infants under 1500 g birth weight), the approximations do not hold.

Reliability: A measure of the repeatability or reproducibility of a clinical measurement. Reliability is sometimes referred to as precision.

Reproducibility: Test reproducibility refers to the degree to which repeated tests on the same sample(s) give the same result.

Reservoir of infection: 1. Any person, animal, arthropod, plant, soil, or substance, or a combination of these, in which an infectious agent normally lives and multiplies, on which it depends primarily for survival, and where it reproduces itself in such a manner that it can be transmitted to a susceptible host. 2. The natural habitat of the infectious agent.

Risk factors: Factors that are associated with an increased likelihood of acquiring disease.

Route of infection: The route by which an etiologic agent gains access to the body of a susceptible individual.

RTE food: Ready-to-Eat food, requiring no further preparation such as cooking

Sample size determination: the mathematical process of deciding, before a study begins, how many subjects should be studied. The factors to be taken into account include the incidence or prevalence of the condition being studied, the estimated or putative relationship among the variables in the study, the power that is desired, and the allowable magnitude of type I error.

Screening: The presumptive identification of unrecognized disease or defect in apparently healthy populations

Seasonal fluctuations: Regular changes in incidence rates with periods shorter than a year.

Secondary case: A group contact of an index or primary case in whom the health condition develops.

Sensitivity: Test sensitivity is defined as the likelihood of a positive test result in individuals known to have the disease or condition being sought. Test sensitivity is sometimes referred to as "operational sensitivity," to distinguish it from "absolute sensitivity," a term used to express the detection limits of an assay.

Serotype (or serovar): a subdivision of a species or subspecies distinguishable from other strains therein on the basis of antigenic character.

Sign: An indication of the existence of something; any objective evidence of a disease, i.e., such evidence as is perceptible to the examining physician, as opposed to the subjective sensations (symptoms) of the patient.

Source: 1. Source of contamination – the person, animal, object, or substance from which an infectious agent passes to a host. The source of infection such as an overflow of a septic tank contaminating a water supply or an infected cook contaminating a salad should be clearly distinguished from the source

of contamination. 2. Source of product – the firm/farm where the product originated. The source of the product is determined through a product traceback investigation. It is not necessarily the source of the contamination or infection.

Specificity: Test specificity is defined as the likelihood of a negative test result in individuals known to be free of the disease or condition being sought.

Sporadic case: occurring irregularly, haphazardly from time to time, and generally infrequently, e.g., cases of certain infectious diseases; also, a case NOT associated with a known outbreak.

Sporadic disease: A disease which occurs rarely and without regularity in a population unit (compare with endemic and epidemic).

Standard population: A population in which the population characteristics of age, breed, sex, etc., are known and used as a standard. When populations are to be compared they should have similar components, and so usually they are mathematically adjusted to have the same proportions as a standard population.

Statistically significant: A level of confidence in the results of a study based on a predefined P value. Generally refers to P values falling below 0.05, i.e., we are willing to be wrong 5% of the time.

Statistically significant association: statistical methods allow an estimate to be made of the probability of the observed or greater degree of association between independent and dependent variables under the null hypothesis. From this estimate, in a sample of given size, the statistical “significance” of a result can be stated. Usually the level of statistical significance is stated by the p-value.

Stop sale: a hold order that can be placed on implicated food that originates from an unapproved source, or that may be unsafe, adulterated, not honestly presented, not labeled according to law or otherwise not in compliance with food regulations. A stop sale prevents the food from being sold to the public.

Strength of association: the magnitude of the measure of association (see above); for example, the size or value of the odds ratio is a measure of the strength of association between an exposure and an illness or other outcome—the larger the odds ratio, the stronger the association.

Study design: the procedures and methods, predetermined by an investigator, to be adhered to in conducting a research project.

Subjective data: Findings such as general condition, alertness, appetite, bowel movements, urination, evidence of pain, etc., which is based on our own observations and those of the owner

Surveillance: the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control. Included are the systematic collection and evaluation of 1) morbidity and mortality reports; 2) special reports of field investigations of epidemics and of individual cases; 3) isolation and identification of infectious agents by laboratories; 4) data concerning the availability, use, and untoward effects of vaccines and toxins, immune globulins, insecticides, and other substances in control; 5) information regarding immunity levels in segments of the population; and 6) other relevant epidemiologic data. A report summarizing these data should be prepared and distributed to all cooperating persons and others with a need to know the results of the surveillance activities. The procedure applies to all jurisdictional levels of public health from local to international. Serologic surveillance identifies patterns of current and past infection using serologic tests. Active surveillance – agencies regularly contact reporting sources to elicit reports of illnesses. An active surveillance system

is likely to provide more complete illness reporting but is more labor intensive and costly to operate. Passive surveillance – agencies receive disease reports from physicians, the public, and institutions as mandated by state law.

Survival cohort: A group of patients who are assembled at various times in the course of their disease, rather than at the beginning, and who are then observed for a period of time to see what happens to them. Generally not considered a true cohort (see cohort).

Survival factors: factors that allow survival or fail to inactivate the contaminant: 1. Insufficient time and/or temperature during cooking or heat processing. 2. Insufficient time and/or temperature during reheating. 3. Inadequate acidification. 4. Insufficient thawing followed by insufficient cooking.

Survivorship curve: Graphic representation of the number or proportion of a cohort of patients with a particular condition remaining at different points throughout the course of their illness. The technique can be used to describe other outcomes of disease besides death, such as recurrence of tumor, remission duration, rejection of graft or reinfection (see life table analysis).

Suspected Case: an illness meeting part of the case definition (see above); for example, specific symptoms (and, perhaps, exposure to a food item of interest) but no laboratory test confirming the cause of the illness; can also refer to laboratory-confirmed illness in persons who are not known to have the exposure of interest.

Suspected food: food from an implicated meal that is a likely vehicle for the causative agent. These foods are often identified in a food specific attack rate table.

Suspected Outbreak: a cluster of cases linked by time or space which have not been confirmed to be caused by the same agent or item (exposure) but which have characteristics (e.g., an unusual organism or exposure) which makes it likely that the cases are linked not by chance alone.

Symptom: Any subjective evidence of disease or of a patient's condition, i.e., such evidence as perceived by the patient; a change in a patient's condition indicative of some bodily or mental state.

Symptomatic: demonstrating clinical signs or symptoms; e.g., having diarrhea, abdominal pain, fever.

Time/temperature abuse: Insufficient time and/or temperature during cooking or heat processing; insufficient time and/or temperature during reheating.

Traceback (also referred to as a product or regulatory traceback): the method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak.

Traceforward: once the source of an implicated food item is established, investigators may do a "traceforward" to document the distribution of all implicated lots of food from the source. This can help epidemiologists with case finding and can be used to test hypotheses about the outbreak. Traceforwards should only be used when there is a reasonable degree of confidence that the traceback correctly identified the source of the implicated product. A product recall also involves a traceforward to determine the suppliers that received the product.

Transmissible (communicable) infection: An infection that can be passed from infected to susceptible animals.

Typical seasonal: Indices of the amount of variation attributable to seasonal influences obtained by averaging (by mean or median) the specific seasonals for each month.

Unapparent infection: The presence of infection in a host without recognizable clinical signs or symptoms. Unapparent infections may be identified by laboratory means, including immunologic tests. Synonyms - asymptomatic, subclinical, occult infection (Benenson, 1985).

USDA: United States Department of Agriculture

Validity: The degree to which a measurement reflects the true status of what is being measured. Another name for validity is accuracy.

Vector: in infectious disease epidemiology, an insect or any living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual or its food or immediate surroundings. The organism may or may not pass through a developmental cycle within the vector.

Vehicle (of infection transmission): the mode of transmission of an infectious agent from its reservoir to a susceptible host. This can be (e.g.) person to person, food, or vector-borne.

Vertical transmission: Transmission of an infectious agent from animals of one generation to animals of the succeeding generation, sometimes transovarially, in utero or with colostrum (see horizontal transmission).

Virulence: A measure of an agent's ability to induce severe disease (see pathogenicity).

Virus: small infectious particle that replicates only in host cell and consists of genetic material, protein coat, and sometimes an outer envelope

Vital statistics: Rates or population indices that provide indirect evidence of the health status of a population. Examples are birth, fertility and death rates (see morbidity rates).

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