

EPIDEMIOLOGY: RISK ANALYSIS



BASICS

OVERVIEW

- Risk analysis is the process to identify, assess, manage, and communicate the impact of a specific risk in a population.
- Risk is comprised of the likelihood of the occurrence of an event and the magnitude of the impact if the event were to occur.
- A hazard is something with the potential to cause harm. Often used interchangeably with risk factor.
- Risk analysis includes three components: 1) risk assessment, 2) risk management, and 3) risk communication.
- Formal risk analysis should be transparent and documented with effective communication to interested parties throughout the risk analysis process.
- Estimating the impact of a given event may be quantitative or qualitative. Quantitative estimates of risk are generally presented as the probability of an event occurring. Various descriptors are used to express risk qualitatively, including negligible vs. non-negligible, and low, medium, and high.
- Evaluation and comparison of risk factors can be done using appropriate study design.
- Cohort, case-control, and cross-sectional studies are types of observational studies commonly used to compare risk. Risk ratio is the most common method of comparing risk in cohort studies while the odds ratio is used in case-control studies.

APPLICATIONS

- Risk analysis can be applied formally or informally to almost any decision-making process in veterinary medicine.
- Import risk analysis is commonly employed in decisions regarding the importation of animals or other agricultural products.
- Animal diseases that are absent or of low prevalence in a given country are at risk of (re)introduction directly or indirectly with increased trade. Consequently, the risk of increased free trade must be assessed, managed, and communicated in order to control the risk as best as possible.
- Risk analysis is involved in the objective determination of risk factors associated with particular animal diseases and their transmission, as well as the relative impact of those risk factors.
- Biosecurity, vaccination, and preventive health programs should be designed after performance of a risk analysis tailored to the individual operation(s) that will be implementing the program(s).
- Risk analysis for transmission of food-borne pathogens is an important role of the food safety veterinarian.
- Antibiotic usage in food animal species is regulated in part by risk analysis of antibiotic residues in food products, particularly as they relate to exposure to humans and the potential for antibiotic resistance.
- The precautionary principle states the introduction of a new product, or the alteration to tested processes, without performing of a risk analysis should be resisted. Or, alternatively, implementation of preventive measures is justified.

COMPONENTS OF RISK ASSESSMENT

RISK ASSESSMENT

- Risk assessment is primarily involved with identifying and characterizing, or quantifying, the true risk.
- Comprised of 5 steps: hazard identification; hazard characterization; release assessment; exposure assessment; and risk characterization.

Hazard identification

- Definition of the hazard in question (e.g., pathogen, management change, altered environment).
- May be derived from published information, surveillance activities, and other sources.

Hazard characterization

- Description of the potential adverse effects associated with a given hazard.
- A dose-response assessment of the hazard should be included when possible.
- Includes route of exposure, mechanism of action, and incubation period.
- Quantitative descriptions are preferred when possible.

Release assessment

- Estimation of the likelihood of a hazard being present and description of the biological pathways by which the hazard may be introduced or released into the environment.
- Qualitative or quantitative

Exposure assessment

- Estimation of the likelihood of exposure to the hazard, including the size of the potential exposed population, and the magnitude and duration of exposure.
- Description of the biological pathways necessary for exposure to the hazard by humans or animals.

Risk characterization

- Description of the probability and severity of consequences due to hazard exposure.
- Integrates results from previous steps to portray the nature and magnitude of the risk.

RISK MANAGEMENT

- Risk management is aimed at implementing control measures to control or mitigate the risk(s) defined by risk analysis.
- Involves the prioritization of risks depending on both the risk likelihood and severity of the potential consequences to hazard exposure.
- HACCP is an example of risk management whereby critical control points are identified and managed to mitigate risk.

RISK COMMUNICATION

- Risk communication involves the dissemination of information on the identified risks and potential control measures to the target audience.
- Encouragement of effective dialogue between all interested parties.
- Perception of risk often differs between risk analysts and other interested parties.
- Transparency and effective communication integral to successful risk management.
- Risk communication should occur throughout the risk analysis process, not as an afterthought or at the end of the risk assessment stage.

OBSERVATIONAL STUDIES TO COMPARE RISK

COHORT STUDIES

- In cohort studies, groups (cohorts) without the disease are assembled and followed to determine the incidence of disease occurrence.

- Generally a group with known exposure to a hazard is compared to a group with no known exposure to determine the risk of developing disease or other consequences.
- Examines groups as they change over time, specifically for incidence of disease occurrence following exposure to a given hazard.
- The risk ratio, or relative risk, is most commonly used to compare risk in cohort studies.
- May be prospective or retrospective. Retrospective studies may also be called historical cohort studies.
- Retrospective cohorts are usually assembled from past records and followed forward, often up to the present. A classic example is the investigation of point source food-borne infection outbreaks.
- Retrospective cohort studies are generally fast and cheap to conduct; the disadvantages include uncontrolled data collection and potentially poor documentation of hazard exposure.
- In prospective, or concurrent, cohort studies, groups without disease are assembled in the present and followed forward into the future.
- Prospective studies provide strong evidence for causation because incidence rates can be calculated directly from observed data without reliance on previous records or memory recall.
- Prospective studies are generally more expensive to conduct and require a considerable amount of time for follow-up, particularly for hazards where the effects of exposure are not immediately evident.
- Prospective studies work well for common diseases and those with short incubation times.

CASE-CONTROL STUDIES

- Case-control studies analyze groups with and without a disease of interest to compare the presence or absence of exposure to a potential risk factor.
- Study groups based on outcome opposed to exposure as in cohort studies.
- Case-control studies are well-suited to study rare diseases and those with long-incubation periods.
- Advantages of case-control studies include their relative quickness, cost-effectiveness and the ability to evaluate the effect of exposure to several different risk factors at once.
- Recall bias, error introduced by differences in the accuracy of recollections by study participants, may be a problem in case-control studies.

CROSS-SECTIONAL STUDIES

- Cross-sectional studies occur at a single point in time and collect information on both disease status and potential hazard exposure simultaneously.
- At study initiation, only the total sample size is determined; the number with or without disease and the number with or without exposure to the potential risk factor are unknown.
- May also be termed prevalence surveys.
- Combines elements of both the cohort study and the case-control study.
- Cross-sectional studies are quick and easy to perform and can be used to determine which of various potential risk factors are associated with an outcome.
- Incidence cannot be measured since no information is gained as to the timing of hazard exposure in relation to disease status.
- Can demonstrate association between risk factors and outcome but does not demonstrate causal effect.

MEASUREMENTS OF RISK

RISK RATIO (RR)

- Ratio of incidence of disease in exposed animals to incidence of disease in non-exposed animals

- RR greater than 1 indicates positive association between risk factor and disease (e.g., $RR = 2$ means twice the incidence of disease in animals exposed to risk factor compared to non-exposed animals). RR less than one indicates a negative association or protective effect. $RR = 1$ suggests no association between factor and disease.
- Also termed relative risk
- Can only be estimated directly from cohort studies.

ODDS RATIO (OR)

- Odds that disease will occur following risk factor exposure compared to the odds of disease occurring in the absence of risk factor exposure.
- OR greater than 1 indicates positive association between risk factor and disease; OR less than one indicates a negative association. $OR = 1$ suggests no association between factor and disease. The higher the OR the stronger the association between exposure and disease.
- OR is a good approximation of RR for rare diseases. OR generally overestimates RR in cases where the rare disease assumption does not hold true.
- OR is used to assess risk in case-control studies. RR cannot be calculated directly in case-control studies because groups are based on disease status, not exposure status.

ATTRIBUTABLE RISK

- The difference in risk between an exposed and unexposed population. Otherwise said, the additional incidence of disease among individuals exposed to a given risk factor
- Used primarily in cohort studies.
- Calculated by subtracting the incidence of disease in unexposed animals (background incidence) from the incidence in exposed animals.
- Indicates the proportion of disease risk that can be attributed to a specific exposure.
- Also called the risk difference or attributable rate.

POPULATION ATTRIBUTABLE RISK

- Difference between the incidence of disease in the total population and incidence of disease in the exposed group
- Indicates the percentage of risk reduction potentially achieved by elimination of exposure to the given risk factor.

ATTRIBUTABLE FRACTION

- Measure of the proportion of disease in the exposed group that can be attributed to the exposure.
- Calculated by dividing the risk difference by the incidence in the exposed group. This proportion can be multiplied by 100 to convert the proportion to a percentage.
- Also called the attributable proportion or the attributable risk percent.
- Estimated directly in cohort studies.

POPULATION ATTRIBUTABLE FRACTION

- Proportion of disease incidence in the population that can be attributed to risk factor exposure.
- Indicates the proportional reduction in disease in a population if risk factor exposure was reduced or eliminated.
- Like the attributable fraction, can be calculated directly in cohort studies but only indirectly in case-control studies.
- Also termed the Population attributable proportion.



DIAGNOSIS

N/A



TREATMENT

N/A



MEDICATIONS

N/A



FOLLOW-UP

N/A



MISCELLANEOUS

ABBREVIATIONS

HACCP = Hazard Analysis and Critical Control Points

OR = Odds ratio

RR = Risk ratio

SEE ALSO

Biosecurity: Beef Cow/Calf (www.fiveminutevet.com)

Biosecurity: Cervidae (www.fiveminutevet.com)

Biosecurity: Dairy (www.fiveminutevet.com)

Biosecurity: Goats (www.fiveminutevet.com)

Biosecurity: Research Herds (www.fiveminutevet.com)

Biosecurity: Sheep (www.fiveminutevet.com)

Epidemiology: Diagnostic Test Use (www.fiveminutevet.com)

Epidemiology: Systematic Approach to Disease Outbreak Investigations
(www.fiveminutevet.com)

Epidemiology: Informatics (www.fiveminutevet.com)

HACCP (Hazard Analysis and Critical Control Point) (www.fiveminutevet.com)

Vaccinology (www.fiveminutevet.com)

Suggested Reading

Peeler, E.J., Reese, R.A., Thrush, M.A. Animal disease import risk analysis--a review of current methods and practice. *Transboundary and Emerging Diseases*. 2015;62:480-90.

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