



COST Action CA17110
Standardizing
output-based surveillance
to control non-regulated
diseases of cattle in the EU

1st Training school

BASIC CONCEPTS IN EPIDEMIOLOGY AND SURVEILLANCE



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CDST Action CA17119



Training school

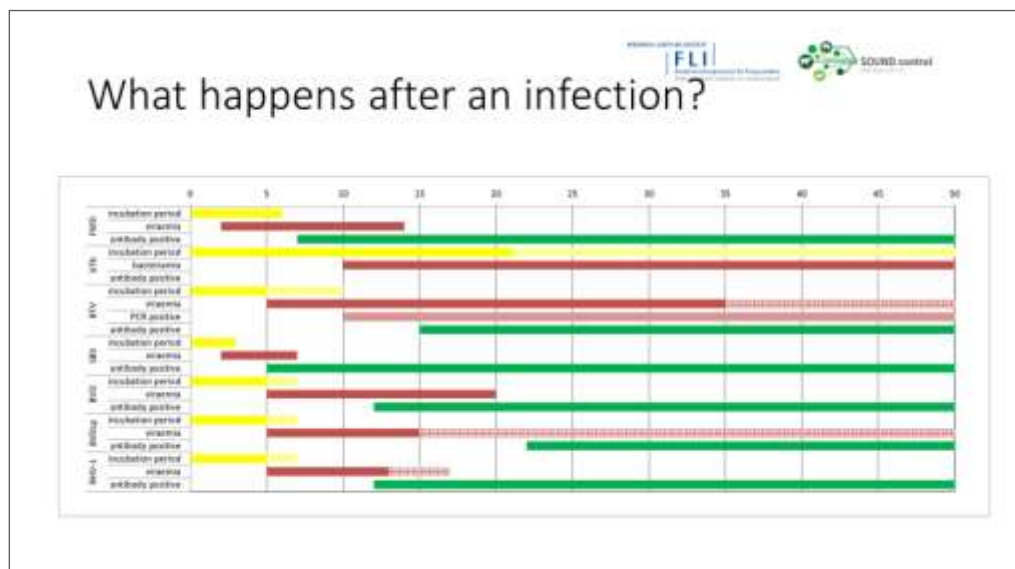
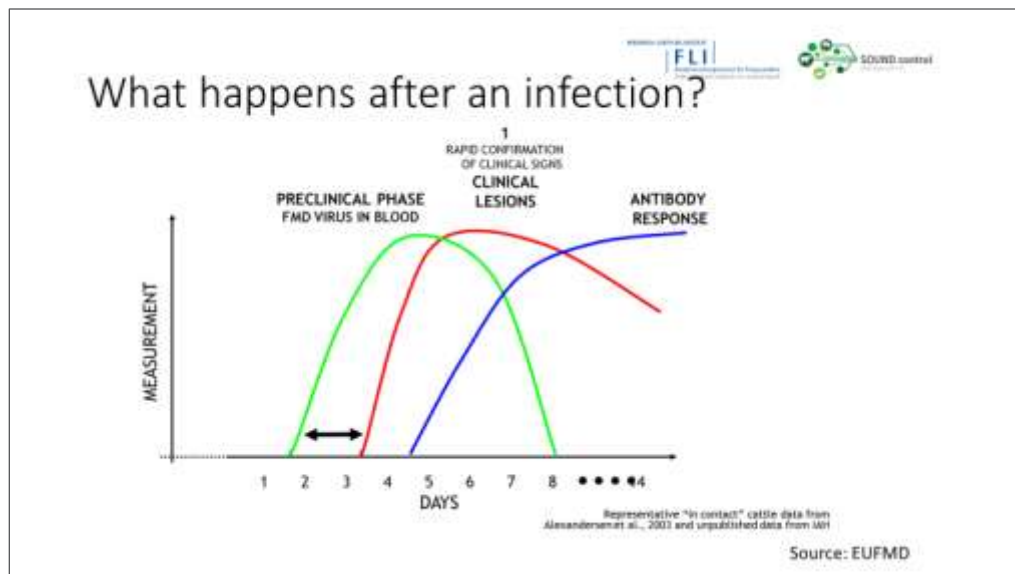
**Basic Concepts in
Epidemiology and Surveillance**

DISEASE MEASURES
Jörn Gethmann, Carola Sauter-Louis



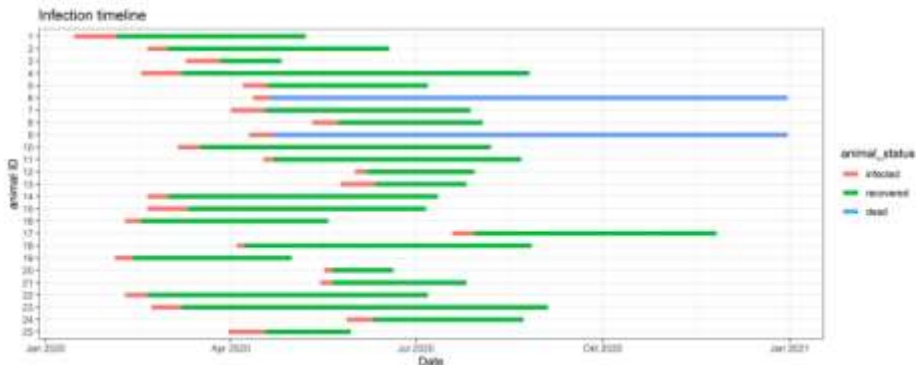






What happens after an infection?

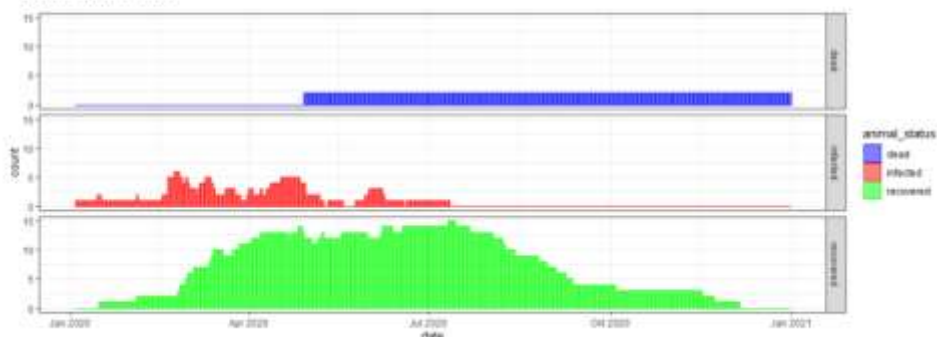
- Virtual farm with 25 animals.
- All animals are at the farm the whole year



What happens after an infection?

- Virtual farm with 25 animals, all animals are at the farm the whole year

Epidemic curve



Case definition

- What is a case?
 - Clinical signs
 - Laboratory diagnostics (PCR, antibody test)
 - Contact to other infected animals?

Your turn (think two minutes about the following questions)

- When do you count a case?
- Discuss the pros and cons?

Go to www.menti.com and use the code 59 45 17 9



Case definition

- As it might be difficult to decide, whether an animal/person is counted as diseased or not, there often is a case definition, e.g.

Article 9

Case definitions

1. The competent authority shall classify an animal or a group of animals as a suspected case of a listed disease or of an emerging disease when:
 - a) clinical, post-mortem or laboratory examinations conclude that **clinical sign(s)**, post-mortem lesion(s) or histological findings are indicative of that disease;
 - b) result(s) from **a diagnostic method** are indicating the likely presence of the disease in a sample from an animal or from a group of animals; or
 - c) an **epidemiological link** with a confirmed case has been established.

Morbidity

$$\text{morbidity} = \frac{\text{number of diseased individuals in a defined period}}{\text{population at risk}}$$

- Proportion of animals diseased (in a defined period) divided by the population (at risk)
- What are „diseased“ animals?
 - Infected
 - Clinically ill
 - Positive tested

Mortality

$$\text{mortality} = \frac{\text{number of dead individuals in a defined period}}{\text{population at risk}}$$

- Proportion of animals died (in a defined period) divided by the population (at risk)

Case fatality

$$\text{case fatality} = \frac{\text{number of } \textit{dead} \text{ individuals in a defined period}}{\text{number of } \textit{diseased} \text{ individuals in a defined period}}$$

- number of animals died (in a defined period) divided by the number of animals diseased (in a defined period)

Incidence

- Incidence relates to the number of new events
- It can be expressed at
 - Incidence count
 - Incidence times
 - incidence risk (R), or cumulative incidence
 - incidence rate (I), or incidence density

Source: Ian Dohoo, Methods in epidemiologic Research, 2012

Incidence risk (R) or cumulative incidence

$$R = \frac{\text{number of newly affected individuals in a defined period}}{\text{population at risk}}$$

- Incidence risk
 - Incidence risk measures the number of new cases over a period of time in the population (at risk)
- Cohort study, monitoring
 - Animals that are diseased at the begin of the study need to be excluded
- Caution: Often wrongly called as „incidence-‘rate’“

Incidence risk (R) or cumulative incidence

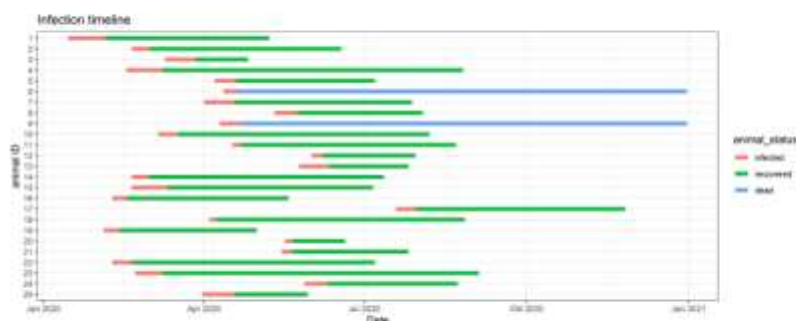
$$R = \frac{\text{number of newly affected individuals in a defined period}}{\text{population at risk}}$$

- What is the „population at risk“?
 - Mastitis

Go to www.menti.com and use the code 21 34 25 5



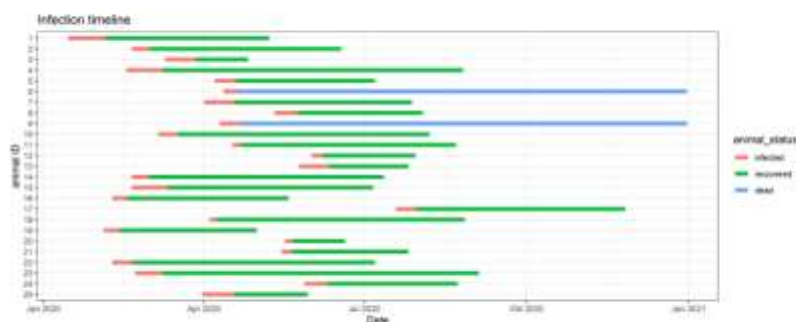
Incidence



- What is the cumulative incidence between 1st January and 31st March?
- When only 10% of the infected animals show clinical signs: How many new cases would have been detected?



Incidence



- What is the incidence between 1st January and 31st March? 12
- When only 10% of the infected animals show clinical signs: How many new cases would have been detected? 1

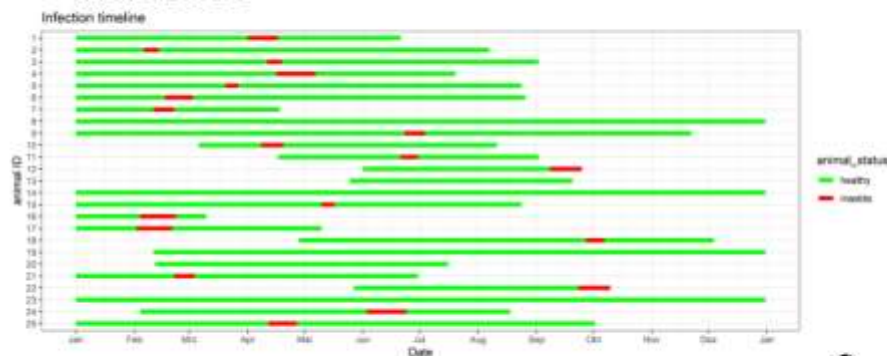


Incidence rate (I) or incidence density

$$I = \frac{\text{number of newly affected individuals in a defined period}}{\text{number of person-time units at risk during the time period}}$$

- Incidence rate
 - Incidence rate measures the number of new cases over a period of time
- Cohort study, monitoring

Incidence



- What is the population at risk?
- What is the incidence rate (time unit month) and incidence risk in the farm in the whole year?



Incidence



- What is the population at risk? All 25 animals
- What is the incidence rate (time unit days) and incidence risk in the farm in the whole year? 19/5209 days= 0.36% or ~19/173 months = 11 %

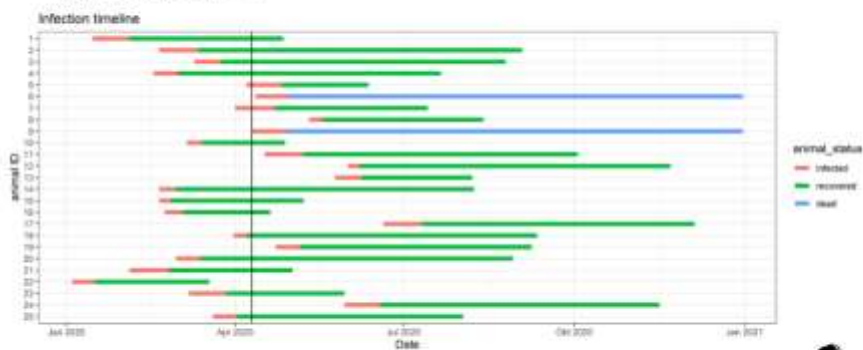


Prevalence

$$P = \frac{\text{number of cases}}{\text{population at risk}}$$

- Prevalence:
 - Proportion of a population found to have a condition.
 - Number of individuals with the disease at a certain point of time among those, which can get the disease.
- Cross-sectional study

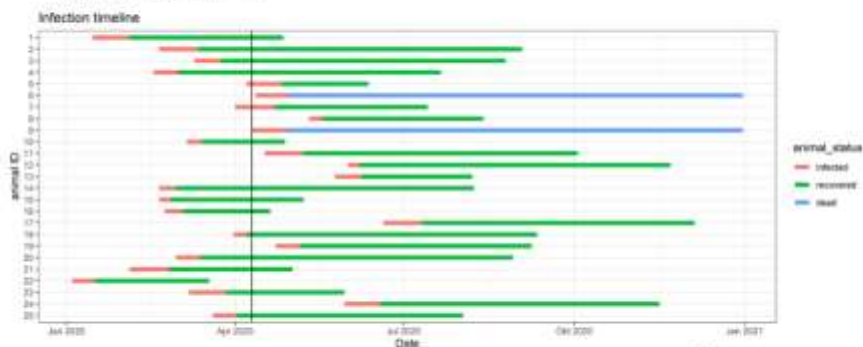
Prevalence



- What is the prevalence at 10th April? (see line)
- What is the difference in prevalence using an antigen/antibody test?



Prevalence



- What is the prevalence at 10th April? (see line)
- What is the difference in prevalence using an antigen/antibody test?

Answer:
Antigen: 2/25 = 8 %
Antibody: 13/25 = 52%

- "Exercise Incidence1.xlsx"
- Calculate the prevalence in December and March
- Calculate the cumulative incidence and incidence density for the year

[illegible]

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Basic Concepts in Epidemiology and Surveillance





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Training school
**Basic Concepts in
Epidemiology and Surveillance**

RISK ANALYSIS
Tanja Knific, Inge Santman-Berends





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Learning objectives

- Understand terms: hazard, risk, ...
- Know the components of risk analysis
- Understand risk analysis reports and studies




Risk analysis





Defintion of Risk



= *a situation involving exposure to danger/hazard*

The possibility that something unpleasant or unwelcome will happen

= probability of occurrence × likely magnitude of consequences (biological and economic)

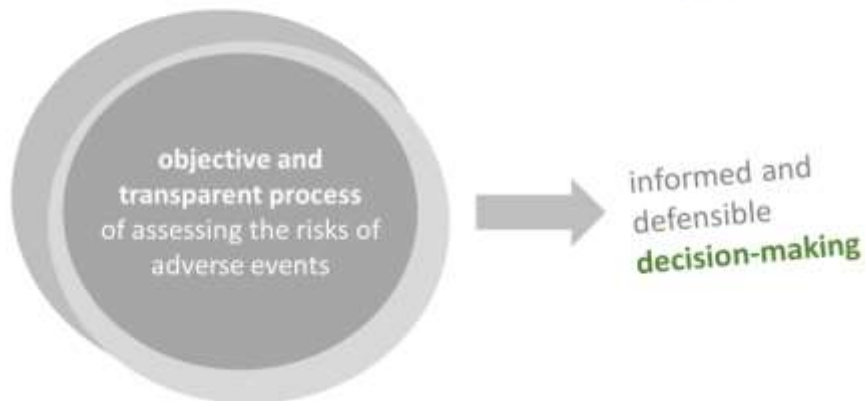
Risk is never 0

Acceptable levels of risk depend on:

- country
- susceptible species (zoonoses)
- morbidity, mortality
- economic consequences
- ...



Risk analysis - WHAT



Risk analysis



Disclaimer

There is no one right way to do a risk analysis.

Risk analysis

WHY: The beginnings



Babylon (3200 BCE) – risky venture, arranged marriage, building site -> advice by priest-like consultant

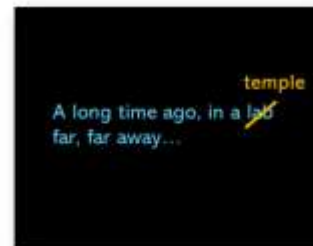
Formal risk analysis (1960s and 1970s)

- nuclear and chemical industries

Microbial risk assessment (early 1990s)

- water quality management
- space exploration

EFSA - 2002



Risk analysis

WHY: The trade awakens



1. Prevention of international disputes
(e.g. EU ban on US beef import)

WTO: Sanitary & PhytoSanitary (SPS) agreement

National health and safety regulations for protection of:

- human health – food safety
- animal health
- plant Health

➤ should not be used as an excuse for protection of domestic industries

2. Prevention of public scare
(e.g. BSE, AI, corona beer ;)



Risk analysis

WHY: The rise of applicability



- rational and objective review of what is known at a particular point in time
- consensus between different stakeholders
- identification of knowledge/data gaps

It never includes all the possible information

- time constraints
- data availability



Risk analysis - WHO



- Food Safety
WHO, FAO, Codex Alimentarius
EC, EFSA
- Animal Health
OIE, Terrestrial Animal Health Code
- Plant Health
FAO, Int. plant protection convention



Risk analysis - WHO



Multidisciplinary team:

- experts on risk-analysis
- scientists – on the topic
- + many other fields
- policy/decision makers
- stakeholders

Requirements:

- broad approach to the problem
- participation of all stakeholders
- extensive data collection



Risk analysis - components



General framework



Hazard identification



Hazard = biological, chemical or physical agent in an animal or animal product with the potential to cause an adverse health effect

Precise question/objective of the analysis

- identify hazard – pathogenic agent
- risk – disease introduction, epidemic, exposure via food
- level – country/region/herd
- time frame

What are possible consequences?

Risk assessment



A scientifically based process, evaluation of

- likelihood and
- biological and economic consequences

Steps - depending on the question

1. Entry assessment
2. Exposure assessment
3. Consequence assessment

Type – depending on the goal, available data

- qualitative
- quantitative



Risk assessment



Collection of information

Define the information needs

Sources

- empirical data - preferred
- literature
- expert opinion



Quantitative vs qualitative



Qualitative

- not in exact probabilities; e.g. low or high risk
- not so detailed
- faster
- applicable in many situations
- subjective perception of meaning of the results
- > inconsistent decisions, ineffective risk management
- useful as a comparative first step

Quantitative

- exact results: probability (distribution)
- in depth analysis
- time consuming
- requires reliable data
- statistical, mathematical models
- better information for decision making
- less ambiguous
- perceived too certain

Qualitative



Qualitative measures of likelihood.

Level	Descriptor	Example description
A	Almost certain	Is expected to occur in most circumstances
B	Likely	Will probably occur in most circumstances
C	Possible	Might occur or should occur at some time
D	Unlikely	Could occur at some time
E	Rare	May occur only in exceptional circumstances

Table 3.4b Qualitative measures of consequence or impact.

Level	Descriptor	Example description
1	Insignificant	Insignificant impact; little disruption to normal operation; low increase in normal operation costs
2	Minor	Minor impact for small population; some manageable operation disruption; some increase in operating costs
3	Moderate	Minor impact for large population; significant modification to normal operation but manageable; operation costs increased; increased monitoring
4	Major	Major impact for small population; systems significantly compromised and abnormal operation; if at all, high level of monitoring required
5	Catastrophic	Major impact for large population; complete failure of systems

FAO/WHO. 2009. Risk characterization of microbiological hazards in food: guidelines. Microbiological Risk Assessment Series 17. Rome. 116 pp.

Qualitative

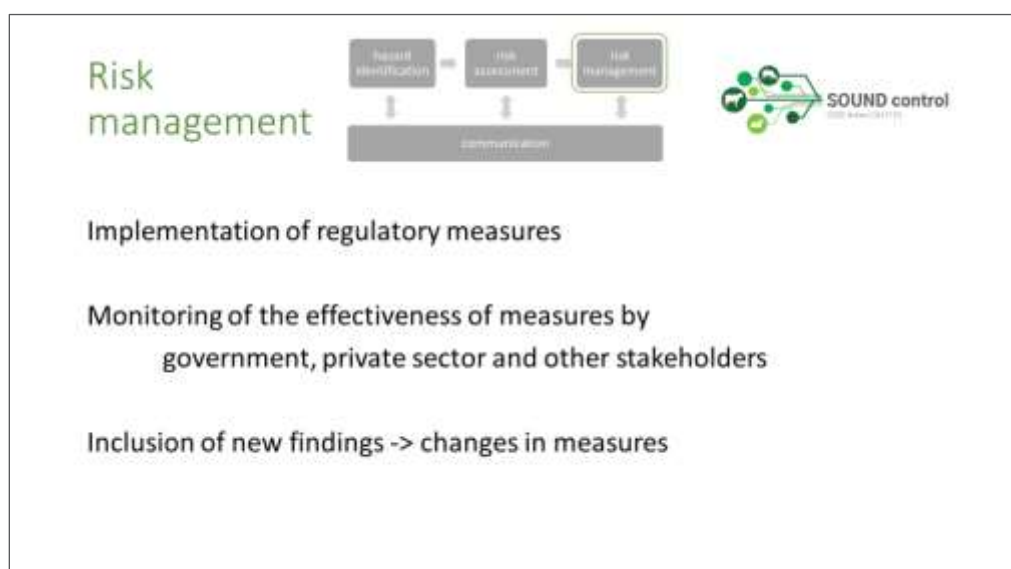
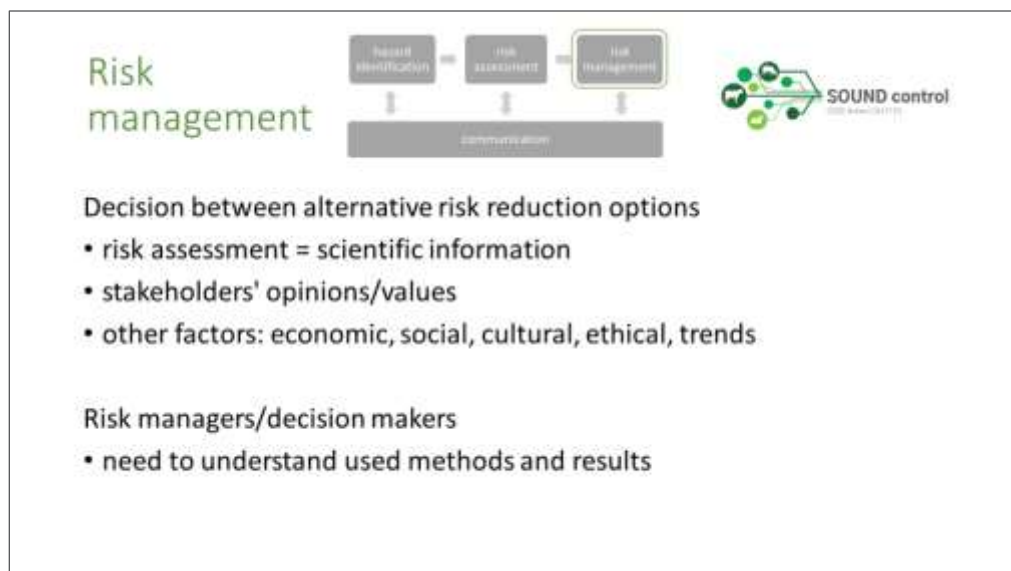
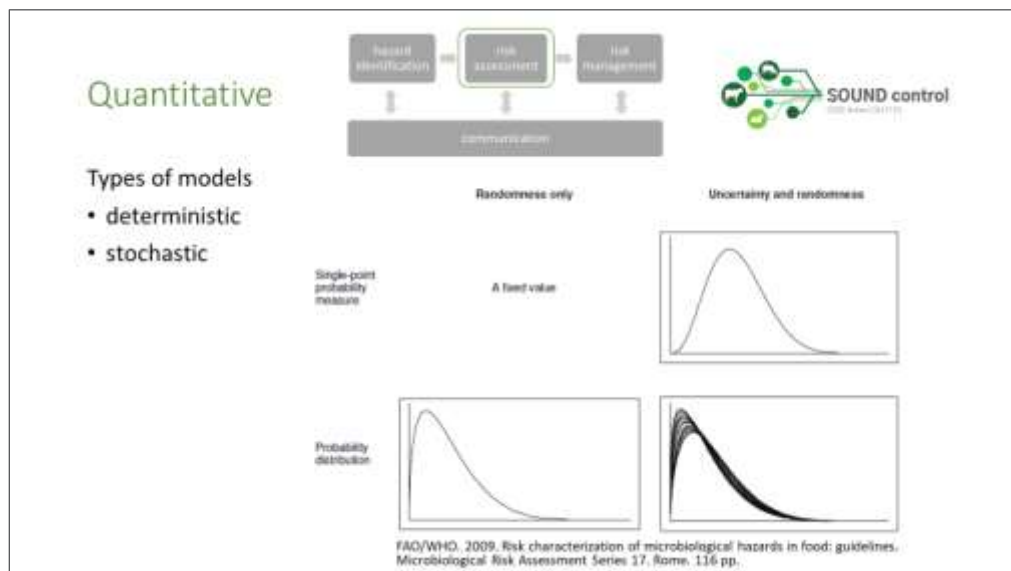


Risk matrix

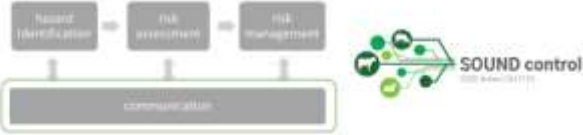
Table 3.4c Qualitative risk analysis matrix: level of risk.

Likelihood	Consequences				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
A (almost certain)	Moderate	High	Very high	Very high	Very high
B (likely)	Moderate	High	High	Very high	Very high
C (possible)	Low	Moderate	High	Very high	Very high
D (unlikely)	Low	Low	Moderate	High	Very high
E (rare)	Low	Low	Moderate	High	High

FAO/WHO. 2009. Risk characterization of microbiological hazards in food: guidelines. Microbiological Risk Assessment Series 17. Rome. 116 pp.



Risk communication




All involved

- risk assessors
- risk managers/policy makers
- consumers + interested parties


Distrust between public and institutions

Public perception of risk

- yes/no
- personal beliefs
- emotional reactions



Risk analysis – END(LESS)




Many feedback loops and steps

The individual steps are repeated:

- as many times as required
- when better information is available

Repetition of interactions between risk managers, risk assessors and other stakeholders!



The big picture



- You are advocate for science
 - what you do and how you do it matter
 - be mindful of your communication with everyone
- Set priorities - this is the only way to know where you are going
- Avoid unnecessary risk - check your relationship with risks in your life
- You are not alone
 - no matter of the problem you have, there are people who had and have the same problem - find data, books, mentors
 - know that hardly anything is only about you – so listen to other people
- *Expectation management* - failure is part of learning



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Training school

Basic Concepts in Epidemiology and Surveillance

Diagnostic Tests

Maria Guelbenzu, Carola Sauter-Louis, Jörn Gethmann



u^b

University of Bonn
Institute for Food Safety and Food Quality (IFSG)

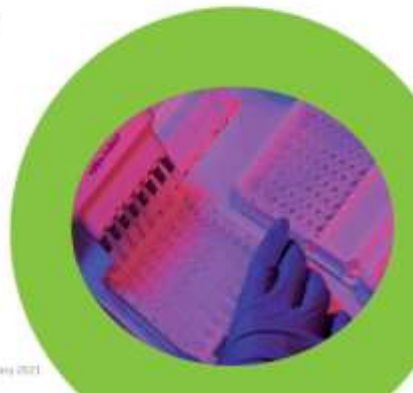
University of Bonn



FLI
Friedrich-Loeffler-Institut
Bundesforschungsinstitut für Tiergesundheit

Contents

- 1) What is a diagnostic test?
- 2) What is Sensitivity (Se) and Specificity (Sp)?
- 3) Two-by-two table & cut off
- 4) Positive and negative predictive value
- 5) Influence of prevalence on PPV and NPV
- 6) Comparison of two test systems ("Gold standard")
- 7) Sequential / parallel testing



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What is a diagnostic test?

- Clinical examination
- Temperature measurement
- PCR analysis of the blood → virological test
- Ab ELISA → test for antibodies

Any device or process design to detect, or quantify, a sign, substance tissue change or body response in an animal. Test can also be applied at herd level or other level of aggregation.



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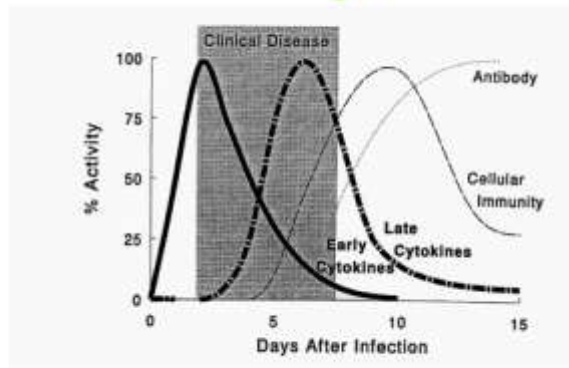
Diagnostic tests

Direct methods

- Culture: slow, low sensitivity
- PCR: high sensitivity and specificity
- Virus isolation

Indirect methods

- Antibody testing
 - ELISA
 - CFT
 - SNT



Campos et al. 1994

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Diagnostic tests



- Screening versus diagnostic
- Analytical sensitivity: lowest concentration of a chemical /organism/substance that the test can detect.
- Analytical specificity: capacity of a test to react to only one chemical compound.
- Accuracy: ability to give a true measure
- Precision: how consistent results are

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Sensitivity and Specificity



- *Sensitivity* is the proportion of true positives that are correctly identified by the test
- *Specificity* is the proportion of true negatives that are correctly identified by the test



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Sensitivity and Specificity



		Condition (as determined by "Gold standard")	
		Positive	Negative
Test outcome	Positive	a	b
	Negative	c	d

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Sensitivity and Specificity



		Condition (as determined by "Gold standard")		
		Positive	Negative	
Test outcome	Positive	True Positive a	False Positive (Type I error) b	a+b
	Negative	False Negative (Type II error) c	True Negative d	c+d
		a+c	b+d	

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Sensitivity



- *Sensitivity* is the proportion of true positives (individuals with the disease) that are correctly identified by the test
- The likelihood of an individual having the disease delivers a positive test result.



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Sensitivity and Specificity



		Condition (as determined by "Gold standard")		
		Positive	Negative	
Test outcome	Positive	True Positive a	False Positive b	a + b
	Negative	False Negative c	True Negative d	c + d
		Sensitivity	Specificity	

$$Se = \frac{a}{a + c} = \frac{TP}{TP + FN}$$

Number of sick animals with a positive test result/ Number of all sick

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Sensitivity and Specificity



- *Specificity* is the proportion of true negatives (individuals without the disease) that are correctly identified by the test (who give a negative result on the test)
- The likelihood that an individual will give a negative test result without the disease.



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Sensitivity and Specificity



		Condition (as determined by "Gold standard")		
		Positive	Negative	
Test outcome	Positive	True Positive a	False Positive b	a + b
	Negative	False Negative c	True Negative d	c + d
		Sensitivity	Specificity	

$$Sp = \frac{d}{b + d} = \frac{TN}{FP + TN}$$

Number of healthy animals with a negative test result/ Number of all healthy

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Sensitivity and Specificity



	True Positive	True Negative
Test Positive	True Positive a	False Positive b
Test Negative	False Negative c	True Negative d
	Sensitivity	Specificity

$$Se = \frac{a}{a + c} = \frac{TP}{TP + FN}$$

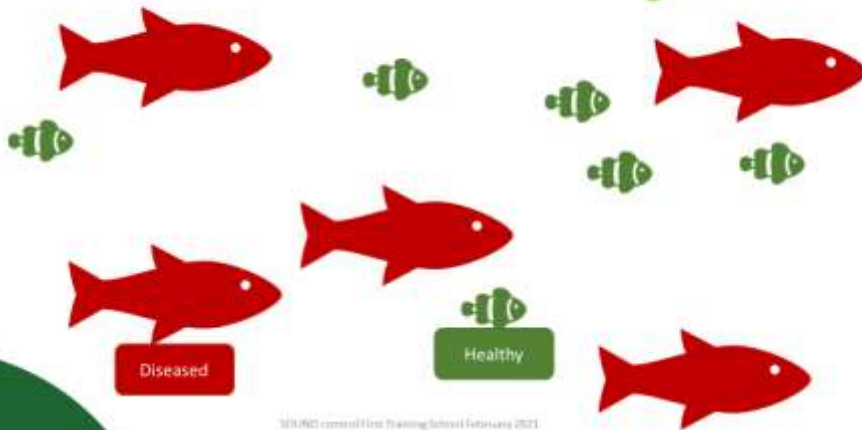
$$FN = 1 - Se$$

$$Sp = \frac{d}{b + d} = \frac{TN}{FP + TN}$$

$$FP = 1 - Sp$$

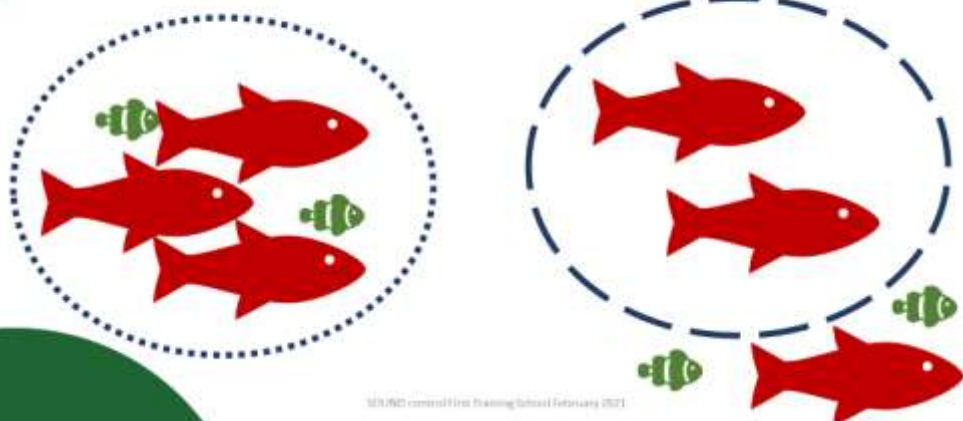
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Sensitivity and Specificity



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Sensitivity and Specificity



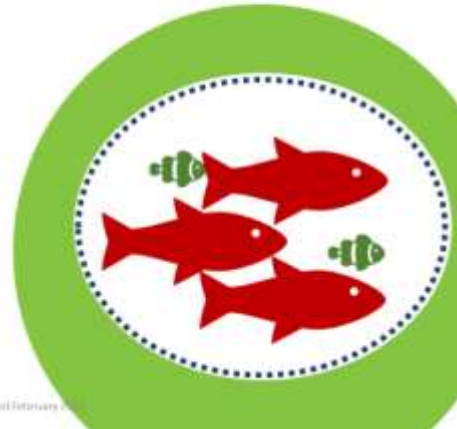
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Sensitivity and Specificity



Sensitivity:

- Tight mesh = high sensitivity
- Fish out many, if possible all, with infection
- Increased false positives
- If ELISA: 99.5% sensitivity
- 995 out of 1000 animals are really positive
- 5 out of 1000 are false negatives



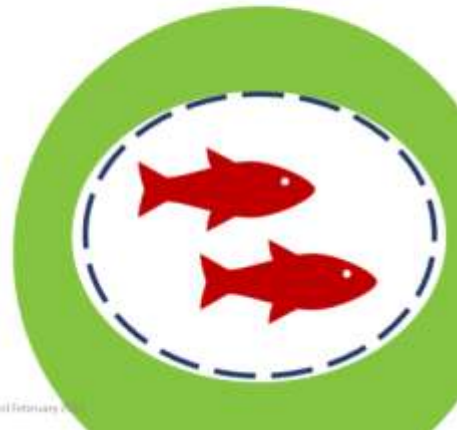
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Sensitivity and Specificity



Specificity:

- Wide mesh = high specificity
- Those who are fished out should really have the disease
- Increased false negatives
- ELISA: 99.5% specificity
- 995 out of 1000 animals are really negative
- 5 out of 1000 are false positives



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Sensitivity and Specificity



Test with: Sensitivity 98%; Specificity 95%;
Prevalence 10%

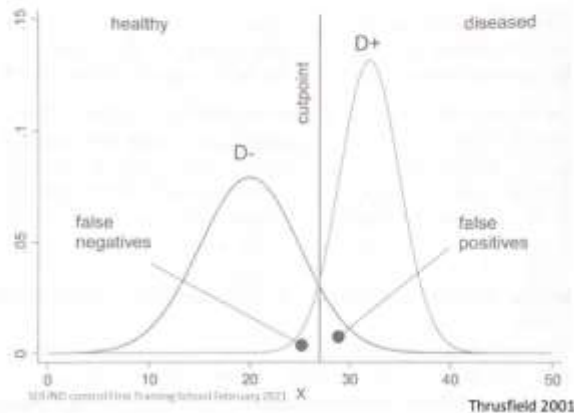
- 50 out of 500 infected
- 49 out of 50 infected detected
- Of 50 infected, 1 false negative
- Of 450 non-infected animals, 22 test positive (false positive)



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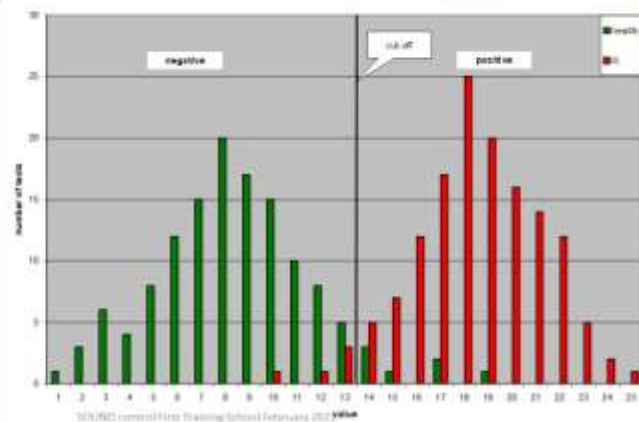
Cut off value

Interpreting test results that are measured on a continuous scale



Cut-off value

value	healthy	ill
1	1	
2	3	
3	6	
4	4	
5	8	
6	12	
7	15	
8	20	
9	17	
10	15	1
11	10	
12	8	1
13	5	3
14	3	5
15	1	7
16		12
17	2	17
18		25
19	1	20
20		18
21		14
22		12
23		5
24		2
25		1



Cut off value

- Depending on purpose: i.e. initial screening – increased Se

Calculation:

- 2 or 3 standard deviations greater than the mean of the test values of the unaffected individuals.
- Values that minimise cost or misdiagnosis
- Calculation of **likelihood ratios**, and construction of **ROC curves**
- **Likelihood ratio**: provides a suitable summary measure of a test's performance, when the test is applied in a population, which is independent of prevalence.

Cut off value



- **Likelihood ratio of a positive test result (LR+)** is the ratio of the proportion of affected individuals that test positive, and the proportion of healthy individuals that test positive.

$$LR+ = \frac{\text{Sensitivity}}{(1 - \text{Specificity})}$$

If $LR+ = 110$, a positive result is 110 times as likely to come from an animal with disease, as from an animal without the disease.

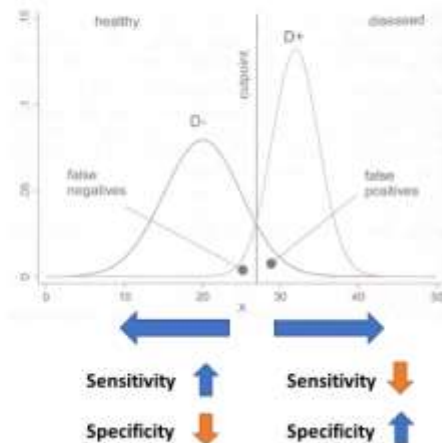
- The **likelihood ratio of a negative test result (LR-)** is the ratio of the proportion of affected individuals that test negative, and healthy individuals that test negative.

$$LR- = \frac{(1 - \text{Sensitivity})}{\text{Specificity}}$$

The $LR+$ for various cut-off values for continuous or ordinal test variables can be presented graphically by drawing a ROC curve

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Cut off



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Positive Predictive Value (PPV)



Predictive value of the positive result of a certain test with regard to a certain disease:

- The percentage of individuals who test positive who also have the disease.
- The likelihood that an individual who tests positive will have the disease.
- The likelihood that a positive test result is really positive.

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Positive Predictive Value (PPV)



		Condition (as determined by "Gold standard")		
		Positive	Negative	
Test outcome	Positive	True Positive a	False Positive b	PPV
	Negative	False Negative c	True Negative d	NPV
		Sensitivity	Specificity	

Sensitivity: $a / (a + c) = TP / (TP + FN)$

Specificity: $d / (b + d) = TN / (FP + TN)$ $PPV = \frac{a}{a+b} = \frac{TP}{TP+FP}$

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Negative Predictive Value (NPV)



Predictive value of the negative result of a specific test for a specific disease:

- The proportion of individuals who test negative who do not have the disease.
- The likelihood that an individual who tests negative will not have the disease.
- The probability that a negative test result is really negative.

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Negative Predictive Value (NPV)



		Condition (as determined by "Gold standard")		
		Positive	Negative	
Test outcome	Positive	True Positive a	False Positive b	PPV
	Negative	False Negative c	True Negative d	NPV
		Sensitivity	Specificity	

Sensitivity: $a / (a + c) = TP / (TP + FN)$

Specificity: $d / (b + d) = TN / (FP + TN)$ $NPV = \frac{d}{c+d} = \frac{TN}{FN+TN}$

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Sensitivity, Specificity, PPV and NPV



		Condition		total		
		Positive	Negative			
Test outcome	Positive	136	7	143	0,951	PPV
	Negative	5	124	129	0,961	NPV
total		141	131	272		
		0,965	0,947			
		Se	Sp			

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Influence of prevalence on PPV



Pop.: 10000; Prev: 20%; Se: 0,98; Sp: 0,99		Condition			→ PPV: 0,960
		Positive	Negative	total	
Test outcome	Positive	1960	80	2040	
	Negative	40	7920	7960	
total		2000	8000	10000	
Pop.: 10000; Prev: 1%; Se: 0,98; Sp: 0,99		Condition			→ PPV: 0,497
		Positive	Negative	total	
Test outcome	Positive	98	99	197	
	Negative	2	9801	9803	
total		100	9900	10000	

Prevalence:

Proportion of individuals in a population who have the disease at a given point in time.

Probability that an individual, chosen at random from the population, has the disease.

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Influence of prevalence on PPV

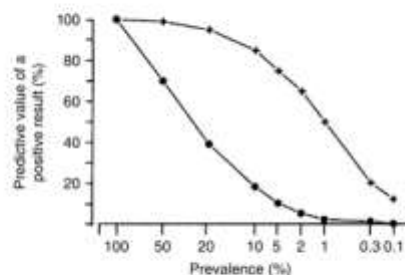


Fig. 20.3 The relationship between prevalence and predictive value of a positive test result. +: Sensitivity = 99%, specificity = 99%; x: sensitivity = 70%, specificity = 70%.

Thrusfield 2001

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Influence of prevalence on PPV



<http://www.winepi.net/uk/index.htm>

Diagnostic

Estimation of predictive values

10% Prevalence

Se 99% Sp 99%

Population 10M

Calculate PPV, TP and FP

- PPV 91.7%
- 990,000 true positives
- 90,000 false positives

0.01% Prevalence

Se 99% Sp 99%

Population 10M

Calculate PPV, TP and FP

- PPV 1%
- 990 true positives
- 99,990 false positives

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Influence of prevalence on PPV



How to increase the PPV?

- Use it in a population with higher prevalence
- Use a more Specific test with same or higher Sensitivity- As Sp increases, so does PPV as the number of false positives approaches zero
- Use more than one test

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Limits of diagnostic tests



- The quality of a diagnostic test determines if I can use it for a special purpose. E.g. a test with a Sp 92% can not be used to detect a threshold prevalence of 1 %
- Se and Sp can be varied by changing the cut off value
- The diagnostic test has to be chosen by looking at Se, Sp and prevalence



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Influence of imperfect tests on sample size



- Sample size increases
- A population can be free even if you have positive test results

Example:

Detection of disease 5% threshold prevalence, 95% confidence, population size 10,000

- 59 samples required with Se 100%, Sp 100%
- 376 samples required, cutpoint no of reactors: 27 with Se 96,5%, Sp 94,7%



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Comparison of two testing systems



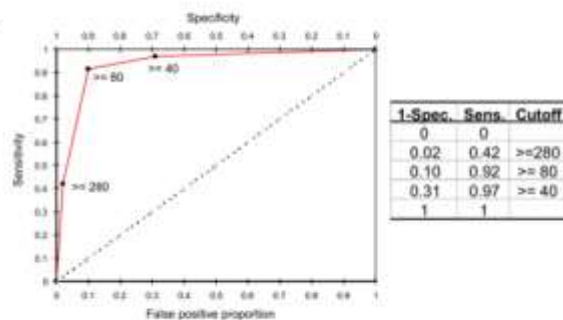
- 'Gold standard' Not always perfect!
- Lower Se in Gold Standard will cause decrease in Sp of the test evaluated
- Lower Sp in Gold Standard will cause decrease in Se of the test evaluated
- Gold standard should be applied to animals (healthy and diseased) that are representative of the population

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Comparison of two testing systems



Receiver-operating characteristic (ROC) curve



Pfeiffer 2002

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Parallel/sequential testing



Parallel testing

- Conducting two or more tests at the same time
- Animals are considered to be affected if they are positive to any of the tests.
- Increases Se and NPV
- Reduces Sp and PPV
- Disease is less likely to be missed – but false positives more likely



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Parallel/sequential testing



Sequential testing

- Conducting two or more tests in sequence (i.e. consecutively)
- Typically, animals are considered to be affected if they are positive to ALL tests.
- Increases Sp and PPV
- Reduces Se and NPV
- Increases the risk that disease will be missed
- Test with highest Specificity should be used first



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Parallel/sequential testing



Parallel	Sequential
Tests performed at the same time. Results are combined.	Second test only performed if the first is positive.
Positive = Any positive result	Positive = All positive results
Higher Sensitivity & NPV Lower Specificity	Higher Specificity & PPV Lower Sensitivity
Rule out a disease	Rule in a disease
Rapid assessment.	Test & removal.

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Parallel/sequential testing



Test :	Test A	Test B
Sensitivity :	80%	90%
Specificity :	90%	99%
Prevalence %:	20	
Population Size :	200000	

	Serial	Parallel
Sensitivity :	72.0%	98.0%
Specificity :	99.9%	89.1%
Positive Pred. Value :	99.4%	69.2%
Negative Pred. Value :	93.5%	99.4%
Apparent Prev. :	14.5%	28.3%
Youden's J :	71.9%	87.1%
Fiability :	94.3%	90.9%
	Dis.	Heal.
Diag.	+	28800 160
	-	11200 159840
	Dis.	Heal.
Diag.	+	39200 17440
	-	800 142560

Winepi.net SOUND control First Training School February 2021

Parallel/sequential testing



Considerations

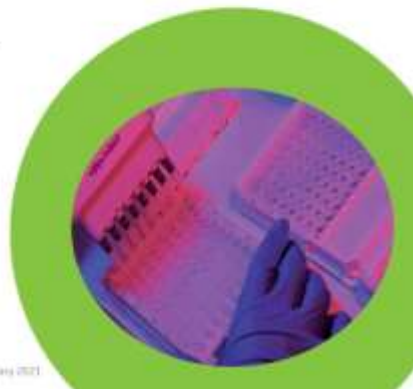
- Test independence: PCR/antibody testing
- Test/disease characteristics:
 - Johne's testing in animals < 2 years old
 - BSE testing < 12 months-old

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Summary



- Diagnostic tests characteristics will influence the quality of data obtained
- Se and Sp can be varied by changing the cut off value
- The diagnostic test must be chosen by looking at Se, Sp and prevalence
- Need to know the disease and test characteristics
- Multiple tests may be used



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Resources



<http://www.winepi.net/uk/index.htm>

<https://epitools.fp7-risksur.eu/tools/index?toolId=44>

<https://epitools.ausvet.com.au/roccurves>

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Thanks for your attention





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CDST Action CA17110

Training school
**Basic Concepts in
Epidemiology and Surveillance**

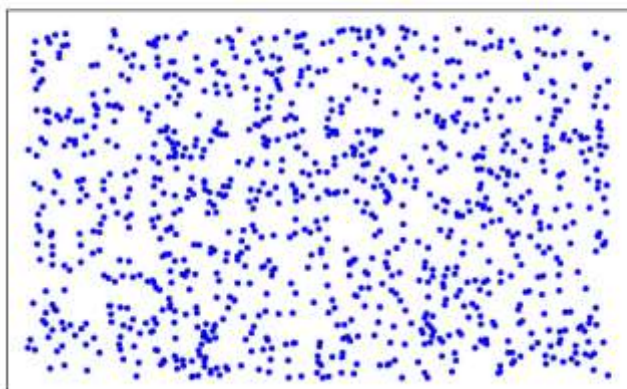
Sample size
Jörn Gethmann, Carola Sauter-Louis




Agenda

- Why sampling?
- Sampling methods
- Mathematical background
- Sample size calculation
 - Detection of disease
 - Prevalence estimation
- Influence of Se/Sp on sample size

Population



N=1000

Status	n
diseased	??
healthy	??

Disease status

How to find out, if and how many animals are diseased?

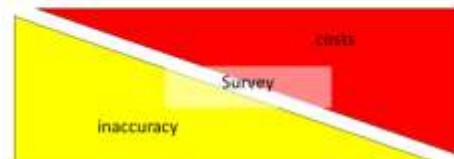
Write your suggestions in the chat



Sampling

- Census
 - **All** individuals of a population are investigated.
 - Only means of measuring the distribution of a variable in population **exactly**.
 - Expensive, difficult
- Sample survey
 - **Some** individuals of a population are investigated.
 - The distribution of variables is estimated
 - Assumption: population consists of representative subunits, characteristics of the aggregate can be estimated from the subunits
 - Less expensive, easier

Thrusfield, 1995



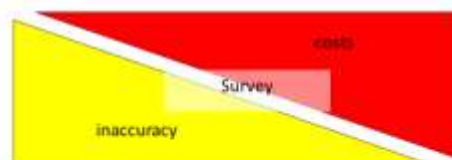
Sampling

What is a sample?

- Only a small proportion (sample) of the population

Why to use a sample?

- Inexpensive and fast
- Monitoring and Surveillance



Sampling

You decided to run a sample survey to find out

- 1) if the disease is present
- 2) How many animals are diseased

Discuss briefly, what you need to know

- To determine how many animals need to be tested
- To decide, which animals have to be tested
- How to perform the sampling

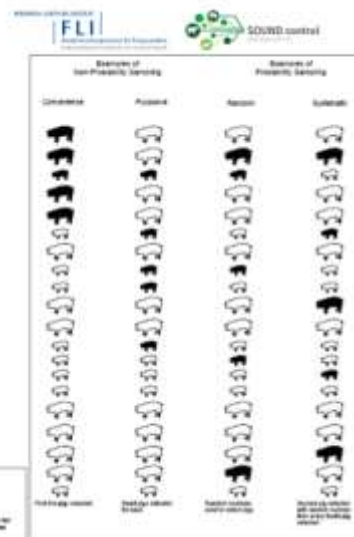


Sampling methods

- Non-probability s. m.
 - Convenience
 - Purposive
- Probability s. m.
 - Simple random
 - Systematic
 - Stratified
 - Cluster
 - Multistage

Source:

Survey Methods for Livestock Diseases
A practical manual with software tools for
data collection and analysis



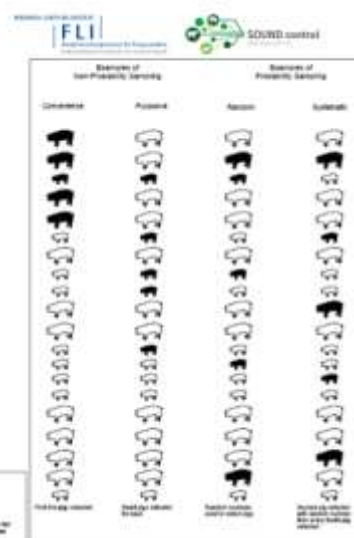
Sampling methods

- Non-probability s. m.
 - Convenience
 - Purposive
- Probability s. m.
 - Simple random
 - Systematic
 - Stratified
 - Cluster
 - Multistage



Source:

Survey Methods for Livestock Diseases
A practical manual with software tools for
data collection and analysis



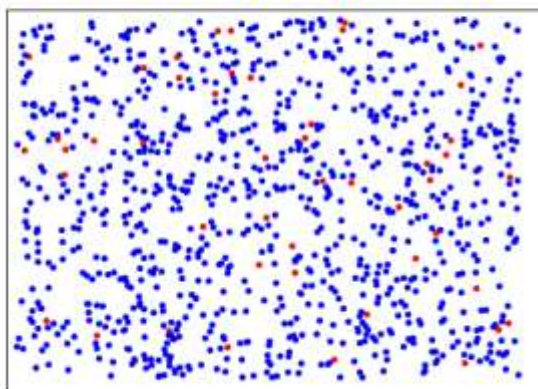
Non-probability sampling

- Convenience sampling
 - Simple
 - Not representative
 - Biased
- Purposive sampling
 - Selection from population
 - No information for the whole population

Probability sampling

- Simple random sampling
 - In the field not "simple"
 - Representative
- Systematic sampling
 - Easier be done than Simple random sampling
 - Bias might be higher

Population

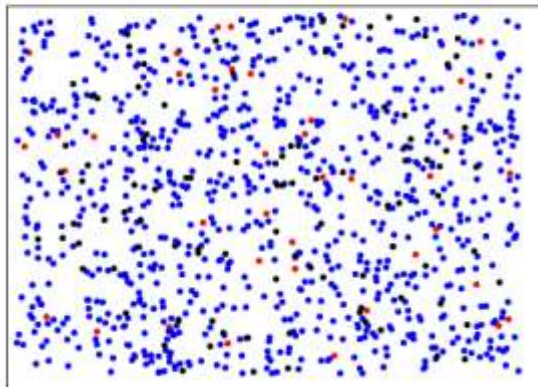


Disease_status
 • diseased
 • healthy

BVD

Status	n
diseased	49
healthy	951

Sampling - random



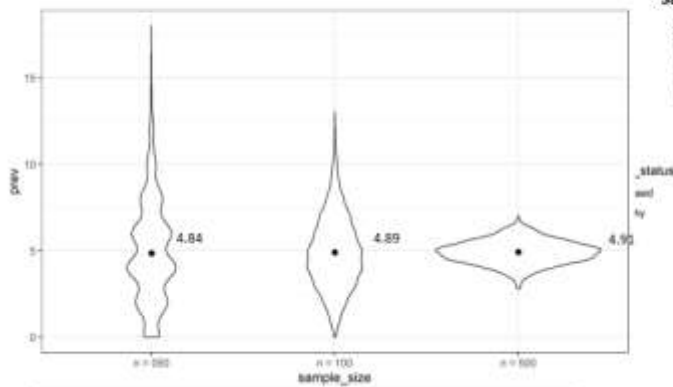
BVD

Status	n
diseased	49
healthy	951

Disease_status
• diseased
• healthy

Sampling

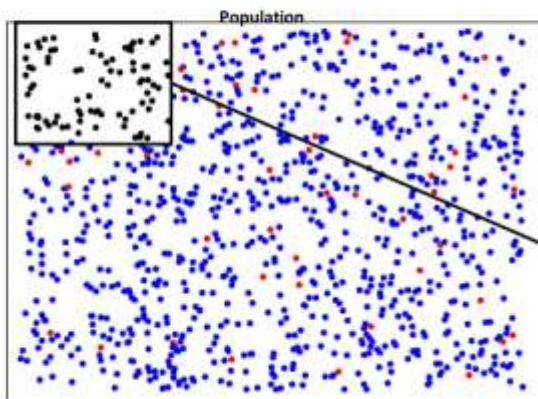
1000 repetitions



Sample of 100 animals

Status	n	P=8 %
diseased	8	
healthy	92	

Sampling - convenience



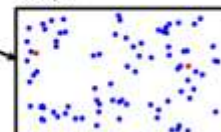
BVD

Status	n
diseased	2
healthy	82

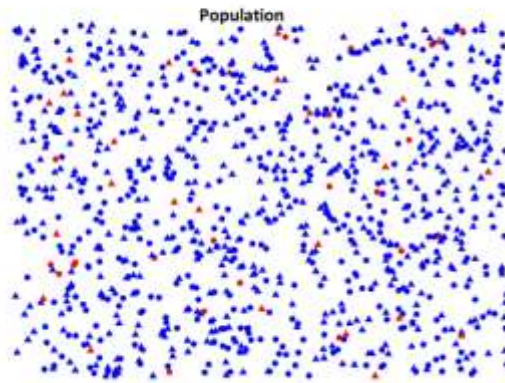
P=2,38 %

Disease_status
• diseased
• healthy

Sample



Sampling



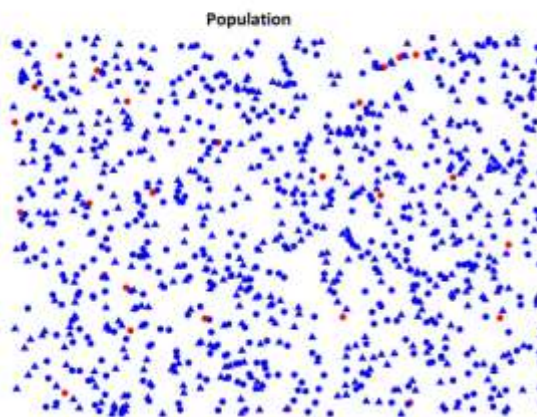
BVD

Sex	Status	n
female	diseased	26
female	healthy	429
male	diseased	23
male	healthy	522

Sex
 ● female
 ▲ male

Disease_status
 ● diseased
 ● healthy

Sampling



Metritis

Sex	Status	n
female	diseased	26
female	healthy	473
male	healthy	501

Sex
 ● female
 ▲ male

Disease_status
 ● diseased
 ● healthy

Sampling -Representativeness



Mathematical background

Sampling and probabilities

Two options

- Sampling without replacement
 - E.g.: lotto, poker, survey
- Sampling with replacement
 - E.g.: to dice



What's the difference?

The population size in sampling with replacement is constant

Sampling and probabilities

1) Sampling without replacement

- Probabilities are changing
- **Not** independent from previous result
 - selecting a certain number with the first ball: $\frac{1}{49}$
 - Selecting a certain number with second ball $\frac{1}{48}$ or $\frac{0}{48}$

2) Sampling with replacement

- E.g.: roll dices
- Probabilities always the same
- Independent from previous roll
- Probability, to roll a 6 is always $\frac{1}{6}$

Sampling and probabilities

1) Sampling without replacement (in general, a survey for animals)

- Calculation more difficult, for large populations not possible (needs factorials, limit in Excel and r 170...)
- With some specific methods large numbers possible

2) Sampling with replacement

- Calculation easy
- No difference in sample size between SwOR and SwR for large numbers
- Can be carried out in all standard apps

Detection of disease

- Sample size estimation (Cannon & Roe (1982)):

$$n = \left(1 - (1 - CL)^{\frac{1}{d}}\right) \times \left(N - \frac{(d - 1)}{2}\right)$$

n = sample size

N = Population size

d = estimated cases in population (design prevalence)

CL = Confidence level (e.g. 95 % = 0,95)

More details at

Survey Toolbox for
Livestock Diseases

A Practical Manual and Software Package for
Active Surveillance in Developing Countries

Detection of disease

- Sample size estimation (Cannon & Roe (1982)):

$$n = \left(1 - (1 - 0.95)^{\frac{1}{(1000 \times 0.05)}}\right) \times \left(1000 - \frac{((1000 \times 0.05) - 1)}{2}\right)$$

$$n = 0.0581 \times \left(1000 - \frac{((1000 \times 0.05) - 1)}{2}\right) = 57$$

n = sample size

N = Population size

d = estimated cases in population (design prevalence)

CL = Confidence level (e.g. 95 % = 0,95)

Prevalence estimation

- Sample size estimation

$$n = \left(\frac{t \cdot \sqrt{p \cdot (1 - p)}}{d}\right)^2 = \frac{t^2 \cdot p \cdot (1 - p)}{d^2}$$

- correction, when n/N < 5%:

$$n(c) = \frac{n}{1 + \left(\frac{n}{N}\right)}$$

- n sample size
- t Student's t-value
- d accepted absolute error or precision (e.g. 5%)
- p prevalence
- n(c) corrected sample size
- N population size

Confidence interval	Student's t-value
90	1,6448
95	1,96
97,5	2,2414
99	2,5758
99,5	2,807

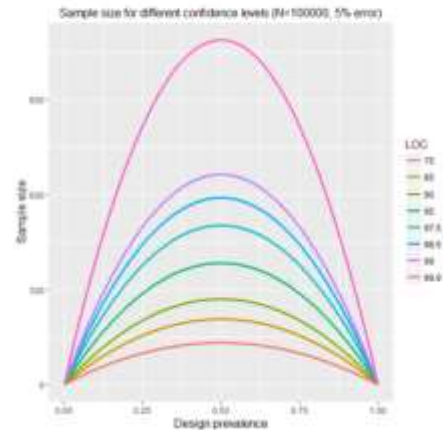
Prevalence estimation

- Highest sample size, when design prevalence is 50%
- Smaller absolute error lead to bigger sample size

More details at

Survey Toolbox for
Livestock Diseases

A Practical Manual and Software Package for
Active Surveillance in Developing Countries



Effect of imperfect tests on sample size

- Previously, we assumed that we have perfect tests
- Please discuss the influence of imperfect tests on
 - Sample size
 - The interpretation of the outcome of the survey
- Does Se or Sp have a higher impact on the sample size?



Go to www.menti.com and use the code 74 76 03 2



Effect of imperfect tests on sample size

- Assume we have a test for our disease with a sensitivity (Se) of 90% and a specificity (Sp) of 99%
- Remember, we have a population with 1000 animals and a prevalence of 5 %
- With CI = 95%, Se=1 and Sp=1 →
- Sample size = 57

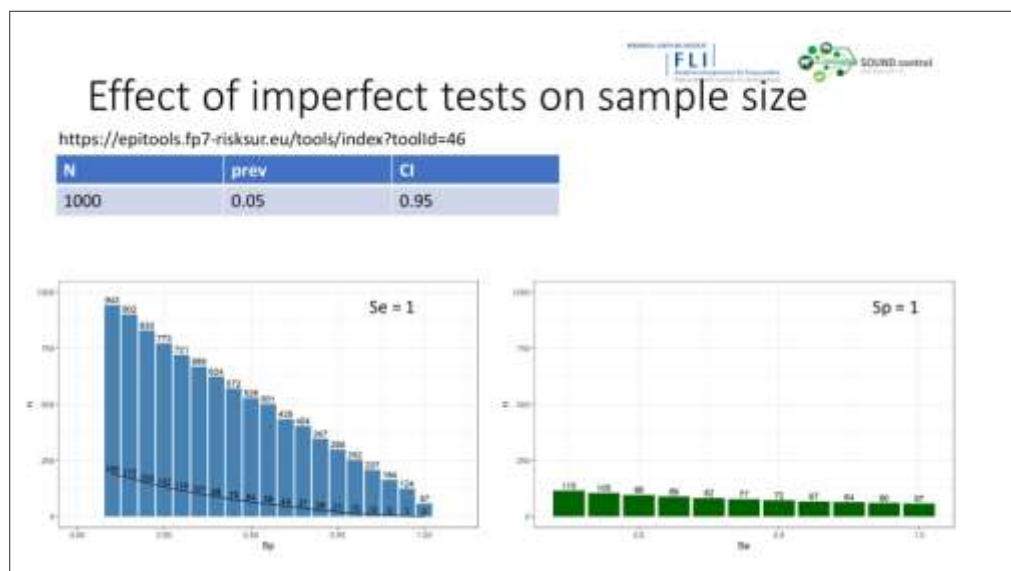
		True value		total		
		pos	neg			
Test	pos	45	9.5	54	ppV	82,57
	neg	5	940.5	946	npV	99,47
total		50	950	1'000		
		Se	Sp			
		90	99	P = 5,00		






Effect of imperfect tests on sample size

<https://epitools.fpi7-risksur.eu/tools/index?toolId=46>

Population size	1000	1000	1000	1000
Test sensitivity	1	0.9	0.9	1
Test specificity	1	0.99	1	0.99
Design prevalence	0.05	0.05	0.05	0.05
Required sample size:	57	136	64	124
Cut-point number of positives:	0	3	0	3
Interpretation:	If a random sample of 57 units is taken from a population of 1000 and 0 or fewer reactors are found, the probability that the population is diseased at a prevalence of 0.05 is 0.0492.	If a random sample of 136 units is taken from a population of 1000 and 3 or fewer reactors are found, the probability that the population is diseased at a prevalence of 0.05 is 0.0491.	If a random sample of 64 units is taken from a population of 1000 and 0 or fewer reactors are found, the probability that the population is diseased at a prevalence of 0.05 is 0.0481.	If a random sample of 124 units is taken from a population of 1000 and 3 or fewer reactors are found, the probability that the population is diseased at a prevalence of 0.05 is 0.0495.



- 

- ## Complex sampling design
- Stratified sampling
 - Useful, if the prevalence between strata shows large differences (e.g. number of positives by age)
 - Information for each stratum needed
 - Random sample in each stratum
 - Summarize results and estimation of overall sample size
 - Cluster sampling and multistage cluster sampling
 - Simple: several clusters (e.g. regional clusters) will be selected and all animals in one cluster will be tested
 - Complex: sample size for clusters and animals will be calculated separately
 - Error on each level
 - Bonferroni correction necessary
 - Examples at
 - <https://epitools.fpi7-risksur.eu/tools/index?toolId=41>
 - <https://epitools.ausvet.com.au/twostageprevalencetwo>

SOUND control
COST Action CA17119

Training school

**Basic Concepts in
 Epidemiology and Surveillance**



SOUND control
CDST Action CA17110

Training school

**Basic Concepts in
Epidemiology and Surveillance**

MONITORING AND SURVEILLANCE
John Berezowski, Jörn Gethmann




What you will learn in this part of the course



- Purpose and outputs of surveillance
- Relationship between surveillance and disease control
- Activities involved in surveillance
- Different types of surveillance, where they are used; their advantages and limitations
- Important concepts to consider when designing a surveillance system

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<http://www.fp7-risksur.eu/project>



RISKSUR

Project Partners Progress News & Events Links Terminology
Challenges | Objectives & Impact | Project Architecture | Facts & Figures

Objectives & Impact

The overall aim of RISKSUR is to develop and validate conceptual and decision support frameworks and associated tools for designing efficient risk-based animal health surveillance systems. RISKSUR will develop tools and frameworks targeted at the following surveillance objectives associated with livestock diseases:

- Detection of incursion of exotic, new (emerging) and re-emerging diseases
- Declaration of freedom from specified diseases and infections
- Monitoring of endemic diseases (base detection, disease frequency estimation)

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Outline



1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design considerations

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1. Introduction



- History
- Who Does Surveillance
- Surveillance Stakeholders
- Surveillance and VPH
- Surveillance Definition
- Monitoring Definition

Outline

- ➔ 1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design

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History of Animal Health Surveillance



- Origins in the reporting of animal plagues of 18th century
- 1924 the OIE was established
- 20th century disease eradication programs
- BSE
- 1995 WTO, SPS, OIE
- Sept 11, 2001
- 2002 EU came into force

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All Countries do Some Animal Health Surveillance



Every country should be able to:

- Describe the diseases that are present (endemic) and their importance
- Prove freedom from important diseases
- Detect - in a timely fashion:
 - New disease introductions
 - Change in important endemic diseases
 - Exotic (transboundary) disease introductions

Required for: international dz reporting and trade
managing disease in national populations

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AH Surveillance Stakeholders



Many:

- Farmers, the public, consumers
- Livestock traders, all farm support industries
- Veterinarians, veterinary associations, researchers
- Government organizations (local, state, national)
- NGOs, producer groups, industry associations
- International Organizations: OIE, FAO, WHO, EU

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Who conducts AH surveillance?



- Governments agencies/organizations
- Academic researchers
- Veterinary practices
- Veterinary associations
- Producers
- Producer/industry associations

Most AHS is conducted by Veterinary Services working as part of state or national governments

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Surveillance in VPH



- Conducted by Veterinary Service Organizations
 - Partnerships with NGOs are common
- For public good
- Under various legislative authorities/regulations
 - International
 - National
 - State/province/canton
- Resources are always limited
 - Expenditures must be justified
 - Efficiency is essential

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Definition of the Word Surveillance



Miriam Webster

- “close watch kept over someone or something (as by a detective)”

Origin:

- French, from *surveiller* to watch over,
- from *sur-* + *veiller* to watch,
- from Old French *veillier*,
- from Latin *vigilare*, from *vigil* watchful
- First Known Use: 1802

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AH Surveillance Supports Action



RISKSUR Definition:

- The systematic, continuous or repeated, measurement, collection, collation, analysis, interpretation and timely dissemination of animal health and welfare related data from defined populations.
- These data are then used to describe health hazard occurrence and to contribute to the planning, implementation, and evaluation of risk mitigation actions

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AH Surveillance Supports Action



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AH Monitoring Does Not Support Action



RISKSUR Definition:

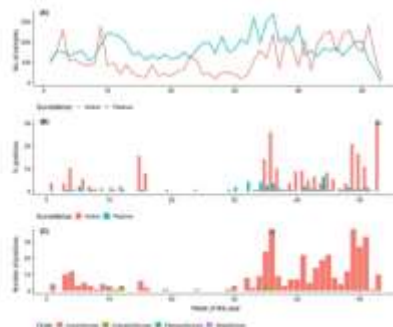
- The systematic, continuous or repeated, measurement, collection, collation, analysis and interpretation of animal health and welfare related data in defined populations
- When these activities are not associated with a pre-defined risk mitigation plan/response
- **HOWEVER:** extreme changes are likely to lead to action.

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AH Monitoring Does Not Support Action



Annual Report on surveillance for avian low path influenza in poultry and wild birds in Member States of the European Union in 2018

- Low Path AI
- Birds are sampled
- Data collected, stored and monitored over time
- No mitigation action

EPSCA Journal, Volume: 17, Issue: 12, First published: 19 December 2018. DOI: (10.2903/epscj.2019.5945)

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2. Purpose of Surveillance



- Theory of surveillance
- Policy purpose and surveillance purpose
- Surveillance and disease control
- Surveillance purposes
 - Early detection
 - Freedom from disease
 - Measuring disease
 - Case finding

Outline

1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design

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The Big Picture



Surveillance reduces the burden of disease (hazard):

- Public health (zoonoses, food safety)
- Animal health, productivity and welfare
- International trade



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What is needed to initiate surveillance?



1. Dissatisfaction

- Occurs when the current state is unsatisfactory compared to a desired state

2. Need:

- For information: the source of dissatisfaction

3. Motivation

- Eliminate the dissatisfaction and meet the information need

*El Allaki F 2012 A population Health Surveillance Theory

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Policy purpose defines the surveillance purpose



Policy purpose:

- How the information produced by surveillance will be used to make decisions relating to animal health, animal welfare, public health, food safety and trade.

Surveillance purpose:

- The type of information produced by surveillance

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Surveillance AND Disease Control

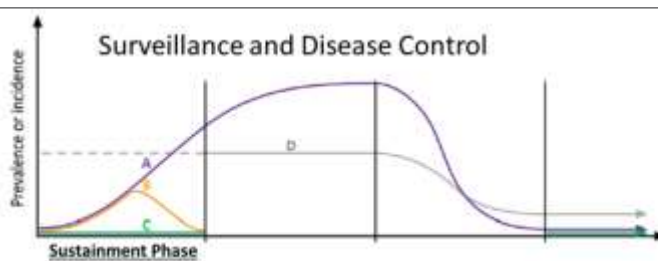
Intimately linked



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The disease may be:

- A. Increasing
- B. Short outbreaks that are successfully managed can occur
- C. Absent
- D. Or there may be uncertainty about the disease. Dashed line

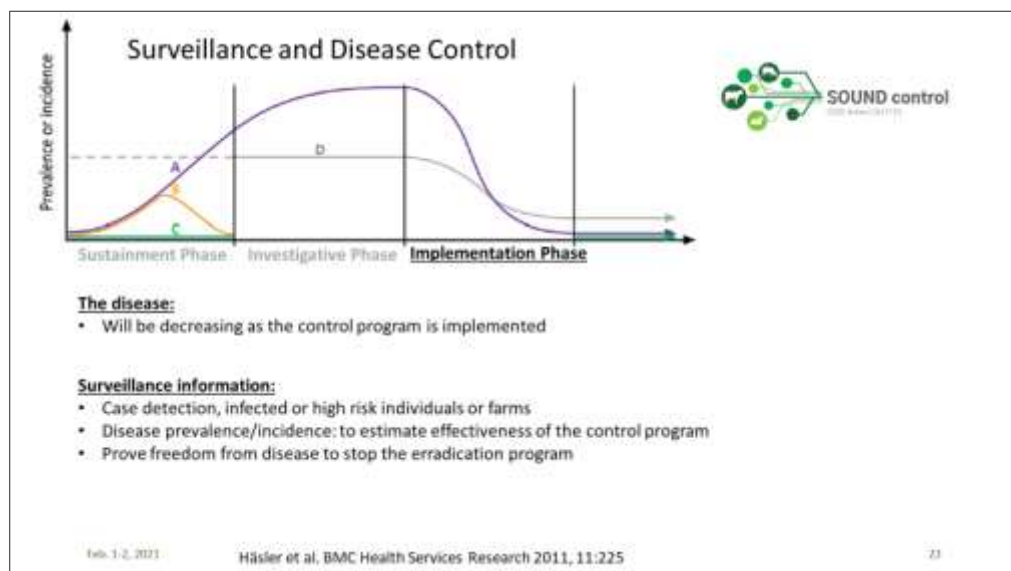
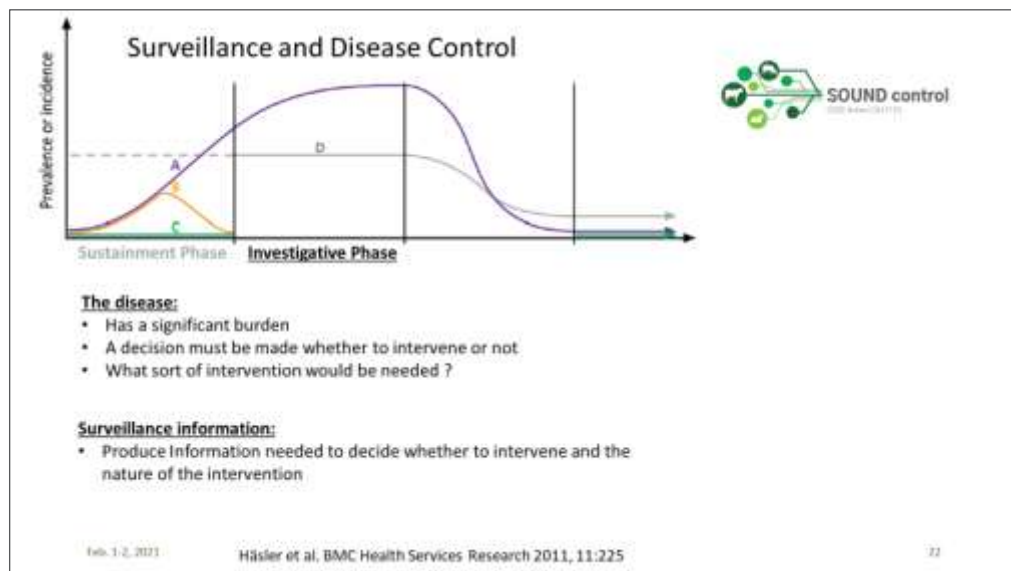
Surveillance information:

- Early detection: emerging or exotic dz incursions: C
- Prevalence/Incidence estimation: A, B, D
- Proving disease freedom: C

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Häsler et al, BMC Health Services Research 2011, 11:225

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BVD in Switzerland



Policy purpose: eradication of BDV

Surveillance purpose: BVD prevalence and finding PI animals

- Sustainment phase: pre-2008
 - Surveillance to estimate the prevalence
- Investigative phase: 2008 census
- Implementation phase: 2008 - 2012
 - 2008: National herd tested for Abv and IHC -> 0.8% of animals and 20.0% of farms were virus positive. All PI animals removed
 - 2008 -2012: Test all newborn calves and remove PI's (decreased from 1.4% to less than 0.02%)
- Sustainment phase
 - Bulk milk sampling of dairy herds and blood testing of beef herds
 - 2015, a total of 111 farms (0.2%) newly infected through PI animals were reported

Surveillance Purpose



The type of Information produced by surveillance

For infectious diseases:

If the disease is absent:

1. Early detection
2. Demonstrate dz freedom

If the disease is present

3. Describe dz (level, distribution, impact)
4. Find cases

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1. Early Detection



Hazards that are:

- New (previously unknown)
- Emerging (changing in importance or region)
- Exotic (FADs, transboundary diseases)

Importance:

- Early response
- Stop pathogen spread
- Reduce the burden of the disease
- Confidence in disease freedom

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1. Early Detection



Goal:

- Detect case occurrences as early as possible
- Early: depends on the rate of disease spread

Surveillance must be:

- Highly sensitive:
 - Detect cases at a low prevalence (design prevalence)
- Broad coverage:
 - Often not possible to predict where a case will appear
- Continuous
 - Often not possible to predict when a case will appear

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1. Early Detection



Surveillance components (usually passive):

- Notifiable/reportable disease programs
- Laboratory testing results
- Slaughterplant surveillance for specific dzes (TB)
- Syndromic surveillance:
 - Veterinary practices
 - Slaughterplant lesions
 - Farm production data
 - Antibiotic sales
 - Laboratory submissions

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2. Demonstrating Disease Freedom



Known hazards that are:

- Exotic (transboundary dzes, FADs)
- Recently completed eradication program
- Country vs compartments

Importance:

- Trade: access to markets
- Population health protection
- Concluding eradication or control measures

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2. Demonstrating Disease Freedom



Goal:

- Provide credible evidence of disease (case) absence

Surveillance:

- Must be sensitive enough to detect cases if they are present
 - Design prevalence is often higher than early detection
 - Dependant on how quick the dz spreads
- Can be intermittent and the evidence updated
 - Even though probability of case occurrence is often continuous
- Valid: sampling is important

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2.Demonstrating Disease Freedom



Surveillance components:

• Active:

- Representative (random) population sampling

• Passive:

- All passive components can be used
- BUT: it is often difficult to estimate the population level sensitivity of passive surveillance.....important

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3.Measuring the level of disease



Hazards that are:

- Endemic diseases
- Cases are present over time

Importance:

- Prioritizing hazards by their importance
- Risk analysis
- Characterizing hazard: geographical, temporal distribution, identifying changes in disease epidemiology

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3.Measuring the level of disease



Goal:

- Provide an accurate estimate of the amount (prevalence or incidence) and distribution of the hazard in the population

Surveillance:

- Precise: lacking random error
 - Sample size
- Unbiased: lacking systematic error
 - Random/representative sampling
- Adhoc, periodic, doesn't need to be continuous

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3.Measuring the level of disease



Surveillance components

- **Active:**

- Representative (random) population sampling

- **Passive:**

- Use with caution!
- All passive samples are biased
- Even before-after a program estimates may be biased

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4.Case finding



Hazards that are:

- Recently introduced or emerged (outbreaks)
- Under control or eradication programs

Importance:

- Stop dz spread in acute outbreaks
- Mop up last cases in eradication programs

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4.Case finding



Goal

- Find all cases (farms/animals that meet the case definition) in the geographic region of interest

Surveillance:

- Sensitive: detecting all cases is essential
- Broad and comprehensive coverage
 - Can be risk-based ie surveillance zones, and tracing
- Continuous

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4. Case finding



Surveillance Components

• Active

- Random/representative sampling of population
 - For slowly transmitted diseases
- Risk-based sampling
 - High risk, incontact farm surveillance

• Passive

- Farmer, veterinary, laboratory reporting
 - Under reporting and failure to report is a problem with stigmatized dzes
- Slaughter plant, auction market surveys
 - Eg, finding TB and Brucellosis cases

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3. Surveillance Activities



- Hazard selection
- Case definition
- Case finding
- Case counting
- Surveillance results
- Communication
- Response

Outline

1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design

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Hazard Selection



- Hazards have the potential to cause adverse health effects
- Biological, chemical or physical agents
- The focus of the surveillance
- The reason for doing surveillance

RISKSUR: A biological, chemical or physical agent
in, or a condition of :
an animal or animal product
with the potential to cause an adverse health effect.

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Hazard Selection



- Defined internationally
 - OIE, EU, WHO, Codex Alimentarius
- Defined by national or regional governments
- Risk-based approaches can be used to prioritize hazards

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Target Population



- The population under surveillance
 - The population about which generalizations will be made
- Further defined by:
 - Species
 - Production sector (dairy vs beef)
 - Geographic region
- Samples, data and observations are collected from the target population

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Case and Case Definition



Animal/Farm + Hazard = Case

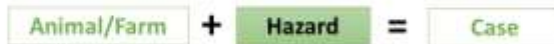
- **Case:** Animal (farm) that meets the case definition
- **Case Definition:** All the criteria needed to classify an animal(farm) as a case....or not
 - May change over time and through stages of the diagnostic process
 - Suspect Case -> Confirmed Case
- Establishing a well thought out case definition is a critical step in surveillance system design

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Case and Case Definition



- Clinical signs or syndromes (including death)
- Pathology (gross/histo)
- Laboratory tests for pathogens or toxins
- Laboratory test for host response (e.g. serology)
- Risk factor(s)
- Indirect indicators (e.g. drug sales, production or performance information, abattoir submissions)

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Case definition



- As it might be difficult to decide, whether an animal/person is counted as diseased or not, there often is a case definition, e.g.

Article 9

Case definitions

1. The competent authority shall classify an animal or a group of animals as a **suspected case** of a listed disease or of an emerging disease when:
 - a) clinical, post-mortem or laboratory examinations conclude that **clinical sign(s)**, post-mortem lesion(s) or histological findings are indicative of that disease;
 - b) result(s) from **a diagnostic method** are indicating the likely presence of the disease in a sample from an animal or from a group of animals; or
 - c) an **epidemiological link** with a confirmed case has been established.

Examples of Case Definitions



Bovine Neonatal Pancytopenia:

- a calf 28-days-old or younger,
- unexplained haemorrhages detected at necropsy,
- Trilineage hypoplasia of bone marrow confirmed by histopathology.
- Trilineage hypoplasia: concurrent depletion of erythroid and myeloid cells and megakaryocytes from bone marrow resulting in less than 25% cellularity

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Lamberton, 2012, Factors Associated with Bovine Neonatal Pancytopenia (BNP) in Calves: A Case-Control Study

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Examples of Case Definitions

Schmallenberg

To facilitate the identification of potential cases of Schmallenberg virus infection, the EFSA produced this checklist of clinical features for fetuses and neonates

intrauterine, premature births, associated fetuses and dysfunctions of fetuses or neonates with two or more of the following:
Arthrogryposis (joint stiffness and limited movement)
Hydrocephaly
Edema
Paralyzed body
Muscle atrophy
Joint malformations
Malocclusion (maloccluded teeth)
Severe curvature of the spine
Myelomeningocele (defect of the spinal cord, sometimes causing a "bathtub" malformation)
Stomach/intestine defects (omphalocele, etc. or "pocket stomach")
Subcutaneous abscesses
Birthmarks



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Tarlinton_2022_The challenge of Schmallenberg virus emergence in Europe

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Case Finding and Counting



Basic activity of surveillance

1. Find cases (animals or farms)
 - Sampling, notification etc
2. Count cases
 - Also count non-cases (denominator)

Increased number of cases : outbreak (epidemic)

Implies knowing the expected number of cases

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Surveillance Results



Since the main activity of surveillance is counting cases..results are expressed as:

- **Incidence:** rate of occurrence of new cases
- **Prevalence:** amount (proportion) of cases in the population

Often presented, or grouped by characteristics of the cases:

- Species, sex, age, geographic region, date (season), production type

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Surveillance Communication and Response



- Communication channels are pre-defined
 - Who will be notified and when
 - Often tightly controlled
 - Premature communication has consequences
- Responses are usually predefined
 - Range of responses
 - Investigation to confirm surveillance results
 - Immediate action: remove carcass, product recall
 - Activation of emergency response plan
 - Policy development

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4. Types of Surveillance



- Active vs Passive
- Risk-based
- Sentinel
- Targeted
- Syndromic
- Participatory
- Indicator vs Event Based
- Survey

How to find cases

Outline

1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design

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Active Surveillance



- Investigator actively seeks out and finds cases
- Investigator decides which animals are sampled
- Most often by sampling the target population
- Eg: A random sample of cattle in Switzerland to estimate the prevalence of BVD

RISKSUR: Investigator-initiated collection of animal health related data using a defined protocol to perform actions that are scheduled in advance. Decisions about whether information is collected, and what information should be collected from which animals is made by the investigator

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Active Surveillance



Pros

- Can be representative of the population
- Valid estimates of population parameters

Cons

- Expensive, labor and resource intensive
- Not continuous, not good for early detection
- May not know the complete sampling frame

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Passive Surveillance



- Investigator does not actively seek caseswaits passively for cases
 - Cases are reported to the investigator from people outside their organization eg. reportable dz programs
- Or Investigator uses data collected for other purposes
 - Using meat inspection data for surveillance

RISKSUR: Observer-initiated provision of animal health related data (e.g. voluntary notification of suspect disease) or the use of existing data for surveillance. Decisions about whether information is provided, and what information is provided from which animals is made by the data provider.

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Passive Surveillance



Pros

- Continuous: good for early detection
- Inexpensive

Cons

- Little control over who submits data/samples
- Not representative of the population
- Some animals not seen by vets, laboratories etc
- Dependant on the willingness of people to report cases:
 - Awareness campaigns vs stigmatized dzes

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Enhanced Passive Surveillance



- Investigator encourages reporting of cases
 - Monetary or other rewards
 - Training, awareness campaigns
 - Indemnity programs for stamping out

RISKSUR: Observer-initiated provision of animal health related data with active investigator involvement e.g. by actively encouraging producers to report certain types of disease or by active follow up of suspect disease reports

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Risk-Based Sampling/surveillance



- Use risk factors to identify subpopulations where cases are more likely to occur or be found
 - Region, season, age, production type, etc.
- Sample in high risk subpopulations
 - Trichinella: focus on farms with outdoor pig rearing

RISKSURE: Use of information about the probability of occurrence and the magnitude of the biological and/or economic consequence of health hazards to plan, design and/or interpret the results obtained from surveillance systems.

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Risk-Based Sampling/surveillance



Pros

- Economical and resource efficient
- Get the information needed using less resources

Cons

- Not a random sample: issues of validity
- BE VERY CAUTIOUS: sample a subset of the population and make inferences about the whole population

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Targeted surveillance



Two meanings for the term:

1. Focused on a specific hazard
 - FMD surveillance
2. Focused on a specific subpopulation
 - Targeted sampling
 - Risk based sampling/surveillance

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Sentinel Surveillance



- Repeated data collection from a subset of the population
- Subset is meant to represent the population
 - Sentinel farms, vet practices, animals
 - Sentinel chickens: represent risk to population

RISKSUR: The repeated collection of information from the same selected sites or groups of animals (e.g. veterinary practices, laboratories, herds or animals) to identify changes in the health status of a specified population over time. These sentinels should act as a proxy for the larger population of interest; they may be selected on the basis of risk but can also be selected randomly or on the basis of convenience or compliance.

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Indicator based surveillance



- Traditional disease surveillance
- Find and count cases
- Analyze data to determine if there indicators of a disease epidemic

RISKSUR: Traditional disease surveillance which relies on the collection of data about the occurrence of pre-defined diseases or conditions and which uses agreed-upon case definitions; these data are analyzed to produce indicators that point towards the existence of a threat

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Event based (media-based, digital) surveillance



- Surveillance of events not individual cases
- Events can be outbreaks/epidemics or events that can be indicative of increased health risk
- Many data sources (WWW, newspapers, gov'ts etc)
 - Promed, healthmap, GPHIN etc
- Requires rapid assessment of the risk

RISKSUR: Surveillance that complements indicator-based surveillance by continuously scanning the Internet and other communication media to detect information that might lead to the recognition of emerging threats

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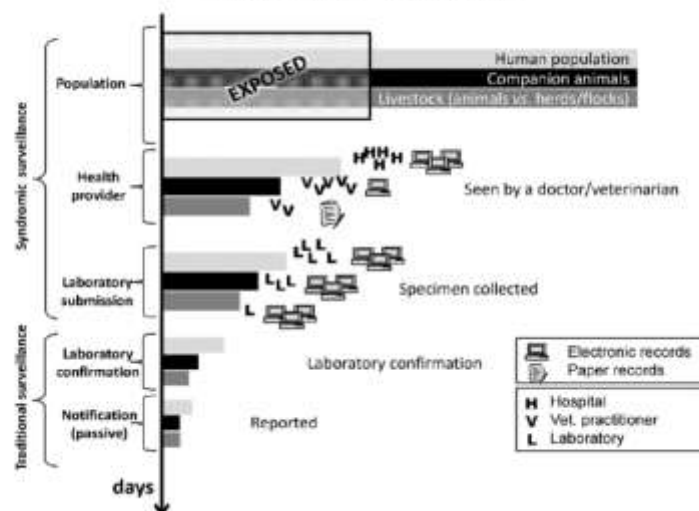
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Syndromic surveillance



- Cases are unconfirmed surrogates for the hazard
 - Pre-diagnostic - before a diagnosis has been made
 - Number of abortions submitted to a laboratory
 - Somatic cell counts in milk
 - Adult cows with diarrhea seen by veterinarians
- May or may not focus on a particular hazard
- Increased counts indicate an increased probability that there is a change in health in the population

RISKSUR: Surveillance that uses health-related information that might precede or substitute for formal diagnosis.



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Participatory Surveillance



- Involving stakeholders IN surveillance activities
- Planning, design, data collection, analysis and response

RISKSUR: Participatory surveillance explores traditional information networks by using participatory rural appraisal methods such as ranking, scoring and visualization techniques to conduct risk-based, hazard-specific surveillance. The approach uses semi-structured interviews with key informants. This enables communities to provide their knowledge regarding health events, risks, impacts and control opportunities by gathering qualitative health data from defined populations.

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Survey



- A survey is not surveillance but can be part of surveillance
- A survey is a tool that is used to measure specific attributes
- Can be used for surveillance, but it can also be used for other activities such as research
- Eg. A questionnaire to survey farmers attitudes
A sero-survey to estimate the prevalence of a disease

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5. Considerations for surveillance design



- Resources
- Hazard characteristics
- Surveillance purpose
- Epidemiology
- Surveillance Characteristics
- Surveillance Components

Outline

1. Introduction
2. Purpose of surveillance
3. Surveillance activities
4. Types of surveillance
5. Surveillance design



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Hazard Characteristics



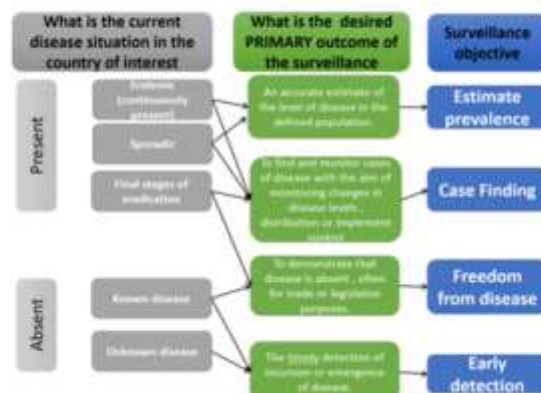
- Present vs absent
- Known or unknown
- High or low prevalence (incidence)
- Long or short incubation
- Rapid or slow transmission
- Clinically distinct or similar to other diseases

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Surveillance Purpose: RISKSUR Design Tool



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Surveillance is based on principles of Epidemiology

Biology and Epidemiology of Pathogens/Dz
Surveillance/Epi Study design
Sampling: size, coverage, frequency, power
Samples: transport, testing method
Data: collection, transmission, cleaning, storage



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Surveillance Sensitivity



Increased Sensitivity = Increased probability of finding cases

- Increase coverage, sample size, reduce the design prevalence
- Broadening the case definition
- Risk-based surveillance
- Incentives for reporting, make reporting easy
- Consider the consequences of reporting
- Use a sensitive test
- Training, technique, quality assurance

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Surveillance Specificity False Positives



Increased Sensitivity = Increased probability of finding cases + Increased False Positives

- Highly specific case definition
- Highly specific test...balance with Se
- Serial testing
- Training, technique, quality assurance
- Proper investigation of Surveillance positive is essential to identify FPs

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Timeliness



- How long it takes to detect and communicate
- Important for early detection
- Make at least one component continuous
 - (or frequently repeated surveys)
- Case definition that includes early dz stage
 - Balance with FPs
- Increased sampling/observing frequency
- Rapid sample collection, transport, confirmatory testing and notification

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Population Coverage



- Important for early detection and case finding
- Target additional susceptible hosts
- Ensure all segments of the population can report
- Case costs must be paid by the investigator
- Public awareness campaigns
- Incentives, indemnity
- Sampling point may affect coverage

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Population Representativeness



- Surveillance accurately reflects the characteristics of the population
- Affects validity of the surveillance
- Case costs must be paid by the investigator
- Public awareness campaigns
- Increase the coverage
- Sampling point may affect coverage
- Collect descriptives to assess representativeness

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Bias



- Poor case definition
 - Use a Se and Sp case definition
- Imperfect diagnostic tests
 - Test with high Se and Sp
- Sampling errors (biased samples)
 - Consider sampling point
- Sample handling and training
 - Poor sample handling can lead to FN or FP

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Bias and Precision



Ensure adequate sample size to meet needs

1. Non-Probability Sampling

- Convenience
- Purposive

2. Probability (Random) Sampling

- Simple random
- Systematic random
- Stratified random
- Risk-based



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Resources



- Increased demands for animal health and food safety information
 - Trade, better or earlier detection because of the constant risk of dz emergence
- Reduced support for veterinary services
 - Balanced against other gov't needs in an environment of fiscal restraint
- Solutions:
 1. Prioritize hazards
 2. Risk-based surveillance
 3. Multihazard surveillance

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Multi-Hazard Surveillance



Surveillance for multiple hazards

1. Parallel design

- Surveillance designed for multiple hazards
- Eg a survey to prove freedom from PRRS and PCV virus

2. Secondary use of samples/data

- Surveillance designed for one hazard (mother component)
- Data or samples are used for other purposes (child components)
- Veterinary practice record surveillance

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Surveillance System and Components



Surveillance system for a specific hazard

- Surveillance made up of components that produce data and information about one hazard
 - For example bovine TB

Surveillance component

- A single surveillance activity that produces data and information about the hazard
 - Examining adult cattle for TB like lesions at slaughter

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Surveillance system for TB in US States



- Prevalence at an all time low in the US
 - Estimated at 0.0006% of population infected
 - 49 states Accredited Free (AF) Status from USDA
- But infected herds identified sporadically
 - Impacts a State's TB Status
- How is surveillance used to help AF States to maintain their status and eradicate bovine TB?

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To maintain Accredited Free Status



Each State must:

1. Make bovine TB reportable by law
 2. Conduct surveillance to demonstrate the prevalence of TB is less than 2% with 95% confidence in cattle and bison populations
 - TB test (caudal fold) on farm
 3. Slaughter surveillance...majority of surveillance
 - In 2007: 5,892,252 cattle were slaughter tested for TB
- Have a veterinary infrastructure that can conduct a TB eradication program

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Convenience sampling



At places where animals are collected

- Slaughter plants, markets, shared pastures

Pros:

- Easy access to large number of animals
- Reasonably good coverage of the population
- Identify possible trends in disease

Cons: biased in many ways,

- Often only healthy animals are presented
- Sick, dead animals are often not brought there
- Valid population estimates are often not possible

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Farmer reporting systems



• Good for

- Early detection
- Demonstrating dz freedom
- Identifying important dzes
- Detecting change over time
- Finding cases

Only for dzes
with unique
and easily
recognizable
signs

• Not good for:

- Any diseases that don't show easily recognizable clinical signs
- Accurately measuring the amount of disease (passive)
- Diseases that are stigmatized

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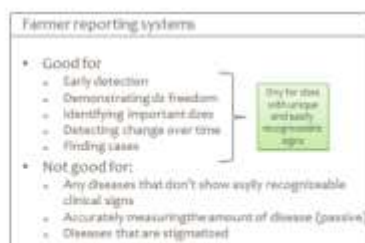
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Veterinary Practices



- Similar to farmer reporting systems
- More specific case classification
- Less likely to not report stigmatized dzes



- Livestock value must support veterinary visits
- Dz must be serious enough to warrant a vet visit

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Veterinary Diagnostic Laboratories



- Good for
 - Previously unknown or unseen diseases
 - When high specificity is required
 - Identifying some trends
- Not good for:
 - Valid population estimates: biased sample
 - Early detection of rapidly transmitted dzes
 - Tests, level of investigation are not standardized
 - Language is not standardized

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Thank You!

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Training school
**Basic Concepts in
Epidemiology and Surveillance**

RISK-BASED SURVEILLANCE
John Berezowski, Jörn Gethmann




RiskSur training material
Katharina Stärk




RISKSUR Training Series - Module 2
Surveillance: Risk-based surveillance

This lecture gives the concepts and methods of surveillance and is developed by the RISKSUR project with the aim of supporting animal health surveillance, and is kindly provided by:

Katharina Stärk
SA/OSO –Switzerland
RVC - UK

 The research leading to these results has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101019719.

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What you will learn in this part of the course



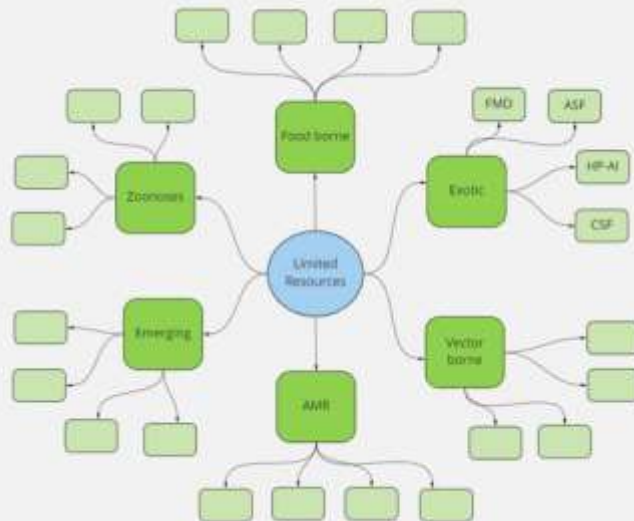
- Principles of risk-based surveillance
- How to apply a simple risk-based approach in the design of a surveillance program
- Similarities and differences between conventional and risk-based surveillance

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The Problem

Limited resources

- Financial, people
- Many hazards



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Information:Cost Ratio



- Need for evidence-based decision making
- Need for documented evidence
- Need for surveillance
- Resources are always limited
- Optimize use of resources



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Katharina Stark <https://www.tpi-virology.eu/progress/teaching-and-outreach>

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Definition



Risk-based surveillance is:

*"a surveillance programme in the design of which **risk assessment methods** have been applied **together with traditional design approaches** in order to assure appropriate and cost-effective data collection"*

Stärk et al. 2006

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Risk Assessment



- An element of risk analysis.
- A systematic and structured approach to collect, organize and evaluate information related to:
 1. the likelihood of an undesired event occurring
 2. its biological and economical consequences.
- **Input:** scientific publications, reports, expert opinion ...
- **The outcome** may be qualitative or quantitative

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Katherine Mark <https://www.tpi-risk.eu/progress/training-and-webinars>

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Risk-based surveillance:



Uses information about:

1. the probability of hazard occurrence
2. the magnitude of the biological and/or economic consequence of health hazards

to plan, design and/or interpret the results obtained from surveillance systems.

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Objectives of RBS



Identify surveillance needed to protect animal health and the health of consumers

- Set priorities
- Allocate resources effectively and efficiently

Evaluation of risk-based surveillance systems should prove that:

- Efficacy of the risk-based approach is equal or higher than that of traditional surveillance;
- **BUT:** the efficiency (cost-benefit) should be higher in risk-based systems.

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Risk-Based Approaches for:



1. Prioritize hazards that have more serious consequences
 - Human health
 - Animal health
2. Prioritize sub-populations (strata) that have higher risk of being infected

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Proioritizing hazard risks



- Probability of event occuring
 - Consider all information available
- Consequences of the event occuring
 - Direct losses: animals, treatment costs, production
 - Costs of disease control: stamping out, quarantine, vaccination

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RBS: Design steps



Risk assessment to select hazards



Risk assessment to select strata



Risk assessment to select products/animals



Random sampling

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RBS: Design steps



Risk assessment to select hazards **Mandated**



Risk assessment to select strata



Risk assessment to select products/animals



Random sampling

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Targeted Sampling or Surveillance



- A specific part of risk-based surveillance

**Target a specific
high risk strata**



Risk assessment to select hazards



Risk assessment to select strata



Risk assessment to select products/animals



Random sampling

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WEE Sentinel Surveillance



Western Equine Encephalitis

- Mosquito borne arbovirus
- Sentinel chickens
- In high risk areas
 - City parks especially with water
- Tested for WEE antibodies
- Sampling of the mosquito pop
- Sampling of the wild bird pop.

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Sentinel herds/animal



Disease, condition	Country	Sentinel animal
Akabane disease	Saudi Arabia	Cattle, sheep and goat
Air pollution	Canada	Cattle
Avian influenza	France, Holland	Birds
Bluetongue	Australia	Cattle
Bovine dermatophilosis	USA	Cattle
Bovine viral diarrhoea virus	Canada	Cattle
East Coast Fever (Theileria)	Zambia	Cattle
Epizootic Hemorrhagic disease	Sudan	Cattle
Internal parasites	New Zealand	Deer
Livestock comfort	USA	Cattle
Lyme disease	USA	Dog
Rift Valley Fever	Mali, Mauritania	Sheep, goat
St. Louis encephalitis	USA	Chicken
Trypanosomiasis	Burkina Faso	Cattle
Vesicular Stomatitis	USA	Horse
West Nile	USA	Crow
Western equine encephalomyelitis	USA	Chicken
Xenotransplantation	USA	Pig

Stärk et al Proceedings of the 11th International Symposium on Veterinary Epidemiology and Economics, 2006

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Risk-based surveillance:



- Uses knowledge of risk factors to improve the probability that we will find the disease or infection.
- Is more efficient at finding disease or infection than representative (random) sampling.
- **BUT:** If we do not know about the disease or any suitable risk factors, it is not possible to use risk-based surveillance.

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Comparison



Steps / elements	Conventional surveillance	Risk-based surveillance
Objectives	The objectives of a surveillance programme are a key determinant of the design.	The objectives of a surveillance programme are a key determinant of the design.
Hazard selection	The hazard of interest (virus, bacteria, disease syndrome) is selected.	The hazard of interest (virus, bacteria, disease syndrome) is selected using risk assessment.
Case definition	Case definition is based on available diagnostic procedures.	Case definition is based on available diagnostic procedures.
Test procedures	Sensitivity and specificity of the diagnostic tests are major determinants of the validity of the surveillance results.	Sensitivity and specificity of the diagnostic tests are major determinants of the validity of the surveillance results.

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Comparison



Steps / elements	Conventional surveillance	Risk-based surveillance
Target population(s)		
Region, location	Usually selected at random.	Selected based on risk factor studies.
Species	Selected based on hazard biology.	Selected based hazard biology and risk factor studies.
Farms	Usually selected at random.	Selected based on risk factor studies.
Animals	Usually selected at random.	Selected based on risk factor studies.
Timing, interval	Usually selected based on the epidemiology of the agent and considering infection dynamics	Usually selected based on the epidemiology of the agent and considering infection dynamics, risk factor studies.

Strata

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Factor used to define high risk strata



Spatial factors

- Climate
- Habitats
- Land use
- Population densities
- Trade
- Wildlife
- Vectors

Host factors

- Animal species
- Age of animals
- Behavior

Management factors

- Biosafety
- Husbandry
- Movement contacts
- Feeding practice
- Antimicrobial usage
- Processing practices

Historical risk

- History of cases
- History of risky practices

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Risk-based sampling



Risk is the product of **likelihood** and **consequences**.

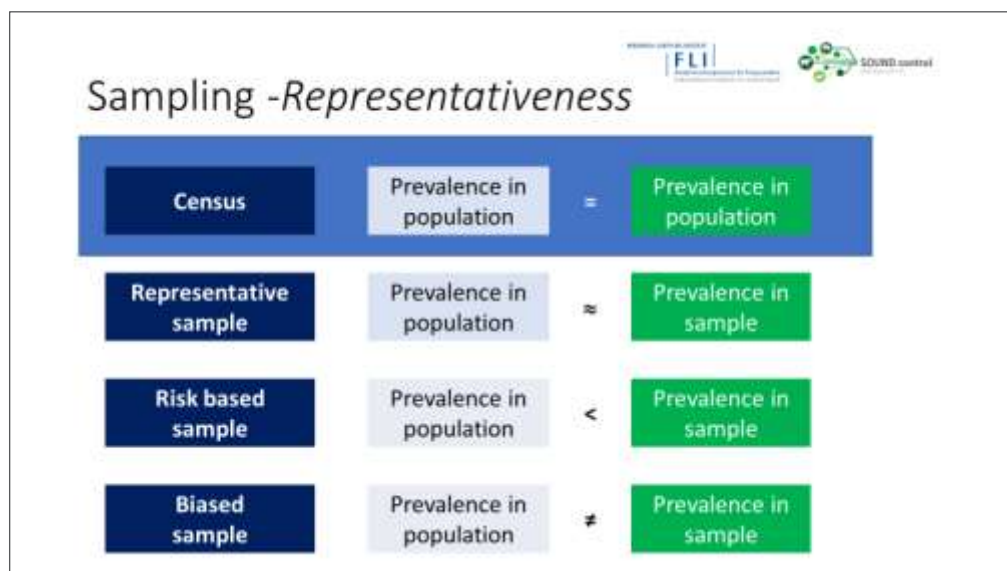
The highest risk strata maybe:


1. The strata with the highest expected prevalence
- OR
2. The strata with the highest hazard impact
- OR
3. A combination of both

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Comparison

Steps / elements	Conventional surveillance	Risk-based surveillance
Statistical analysis, outcome	Standard statistical analyses	Standard statistical analyses and additional analyses for comparison to conventional surveillance
Communication of results	A series of options are available: Oral, written, web, media etc.	A series of options are available: Oral, written, web, media etc.
Consequences of positive outcome	The action steps following positive results need to be determined and organized.	The action steps following positive results need to be determined and organized.
Feedback mechanisms	Feedback to the people involved in data collection is essential for quality assurance.	Feedback to the people involved in data collection is essential for quality assurance. Inclusion in risk assessment.

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Risk-based surveillance cycle



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Examples of RBS



- BSE
- H5N1
- Trichinella

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CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY



ANEXO 11.4.1

- First important surveillance system with risk-based design
- BSE is very rare, expensive to diagnose, only in dead animals
- The incubation period is extremely long (years)
- Clinical signs may be subtle and unspecific
- Exit route is a key risk factor:
 - Emergency slaughter
 - Non-ambulatory
 - Routine slaughter
- BSE is very important for trade
- International surveillance standards apply

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BSE surveillance – risk assessment



OEI Animal Health Code, 2014⁹

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,800	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500

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https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_bse.pdf

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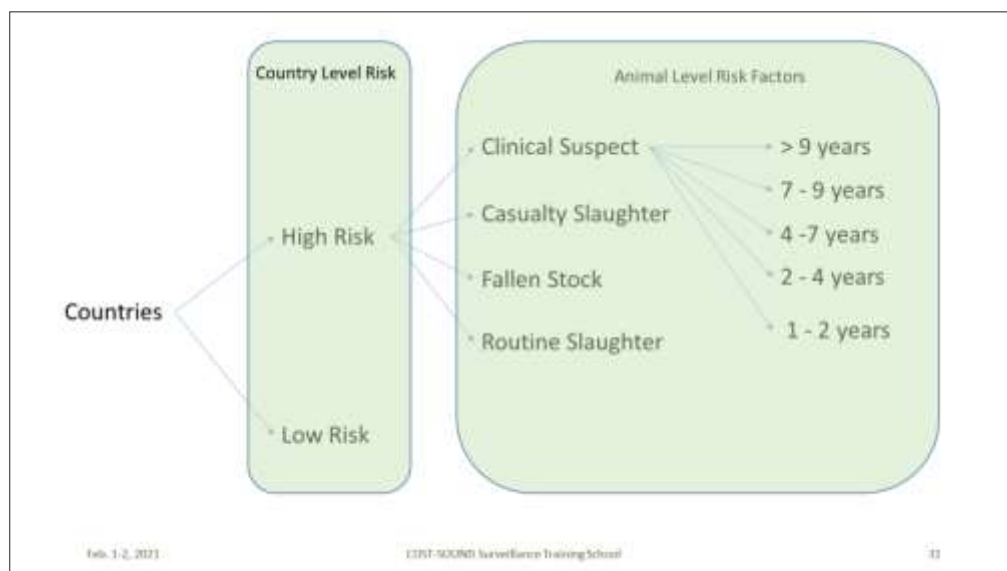
Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
Routine slaughter ¹	Fallen stock ²	Casualty slaughter ³	Clinical suspect ⁴
Age ≥ 1 year and <2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and <4 years (young adult)			
0.1	0.2	0.4	200
Age ≥ 4 years and <7 years (middle adult)			
0.2	0.5	1.6	750
Age ≥ 7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years			
0.0	0.1	0.2	45

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https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_bse.pdf

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Risk-based surveillance for H5N1 avian influenza virus in wild birds in Great Britain

L. C. SNOW, S. E. NEWSON, A. J. MUSGROVE, P. A. CRANSWICK, H. Q. P. CRICK, J. W. WILESMITH



- Infections with highly pathogenic AI viruses occur in domestic and wild birds
- Infection is rare
- Susceptibility varies greatly between bird species
- Clinical disease in domestic poultry is severe
- Mostly sub-clinical in wild birds
- Wild birds pose a significant risk to domestic poultry

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H5N1 AI Surveillance



Surveillance purpose: early detection of H5N1 in poultry

Geographical surveillance units

Estimate the risk of transmission per 10 KM² areas

For each 10 KM² area:

1. Probability of AI introduction by wild birds
2. Presence of poultry
3. Combine 1 and 2 for an overall risk estimate

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Probability of Introduction

- For each 10 KM² area:
- Estimate abundance of each species (24)
- For each species
 - Probability of being infected
 - Abundance
 - Seasonal patterns
 - Known to mix with domestic poultry
 - Social behavior (flocks vs solitary)



FIG. 1 Map showing risk of introduction of avian influenza virus based on the abundance of wild birds in the UK and the probability of being exposed to the virus outside the UK and the probability of being exposed to the virus outside the UK.

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Poultry Risk

- For each 10 KM² area:
- Number of poultry
 - Consequences and risk of infection
- Production type
 - Hatchery vs broiler vs layer
 - Commercial vs backyard
- Environment in which birds were kept
 - Indoors vs free range vs access to a pond
 - Distance to ponds, rivers, lakes
- Mix of quantitative and qualitative
 - Ranked risk (1-6)

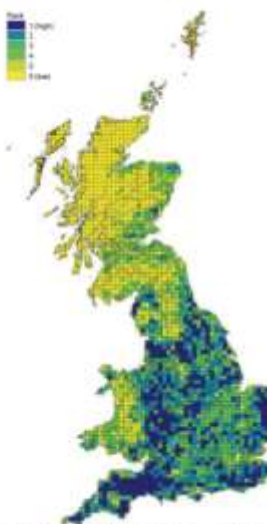


FIG. 2 Map showing the risk of introduction of avian influenza virus to domestic poultry based on the abundance of wild birds in the UK and the probability of being exposed to the virus outside the UK.

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Risk of Introduction



FIG. 1 Map showing risk of introduction of avian influenza virus based on the abundance of wild birds in the UK and the probability of being exposed to the virus outside the UK.

Poultry Risk



FIG. 2 Map showing the risk of introduction of avian influenza virus to domestic poultry based on the abundance of wild birds in the UK and the probability of being exposed to the virus outside the UK.

Combined Risk



FIG. 3 Map showing the combined risk of introduction of avian influenza virus based on the abundance of wild birds in the UK and the probability of being exposed to the virus outside the UK.

Advantages - Disadvantages



Conventional

- + Many methods available
- + Well validated
- + Commonly accepted
- Expensive
- Low information content (all negative)
- Not efficient

Risk-based

- + Higher benefit:cost ratio
- + More efficient
- + Suitable for rare events
- Data availability
- Analytical methods still need to be developed
- Equivalence assessment not yet developed
- Acceptance?

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Would you accept live pigs from Italy?



- ASF is likely to enter from the north
 - Transmission among wild boar
 - Transmission to wild boar
- Test all hunter, road killed, and found dead wild boar above the red line AND all tested negative
- Would you accept live pig imports from Italy?

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CWD Surveillance



Chronic Wasting Disease
In Wild Deer

In Saskatchewan

Not in Alberta

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CWD Surveillance



Chronic Wasting Disease

In Wild Deer

In Saskatchewan

Not in Alberta

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CWD Surveillance



Chronic Wasting Disease

In Wild Deer

In Saskatchewan

Not in Alberta

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When to use Risk-Based Approaches?



It depend on the objectives!

Component of Risk Assessment:	Likelihood	Consequences:	
		Prove Dz Freedom	Early Detection
Prioritize Hazards	Yes	Yes	Yes
Selection of Stratum	Yes	No	Yes
Selection of units within strata	No	No	No

A Random Sample

Providing freedom from disease requires evidence from all strata.

Complex Surveillance Systems



- Multiple components
- Multiple active and passive components
- Traditional and risk-based
- Many data sources
- Integrated into an overall surveillance system

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Brucellosis and Tuberculosis



Active:

- Triannual survey

Passive:

- Reportable disease
- Slaughter plant surveillance

Risk-based:

- Random sample of farms in high risk area
- Test all adults at markets around parks

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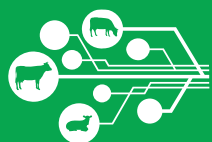


Thank You!

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Cooperation in Science and Technology



SOUND control
COST Action CA17110

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Training school BASIC CONCEPTS IN EPIDEMIOLOGY AND SURVEILLANCE



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