Food and Agriculture Organization of the United Nations

FAO/China Intensive Training Course on Tilapia Lake Virus (TiLV)

Sun Yat Sen University, Guangzhou, China

18-24 June 2018

Session 4

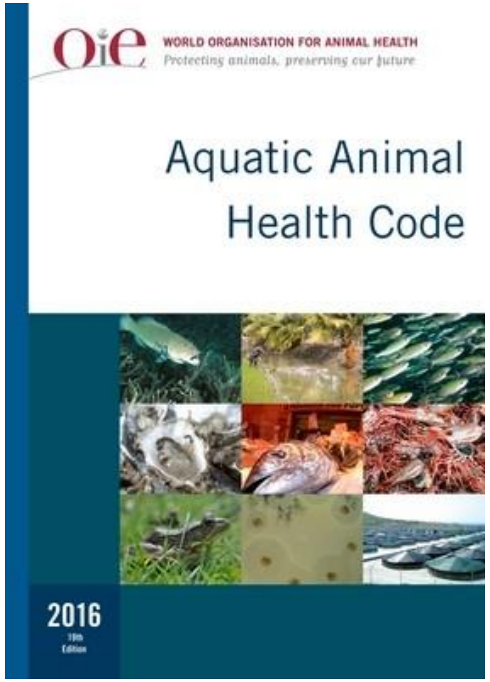
Mona Dverdal Jansen

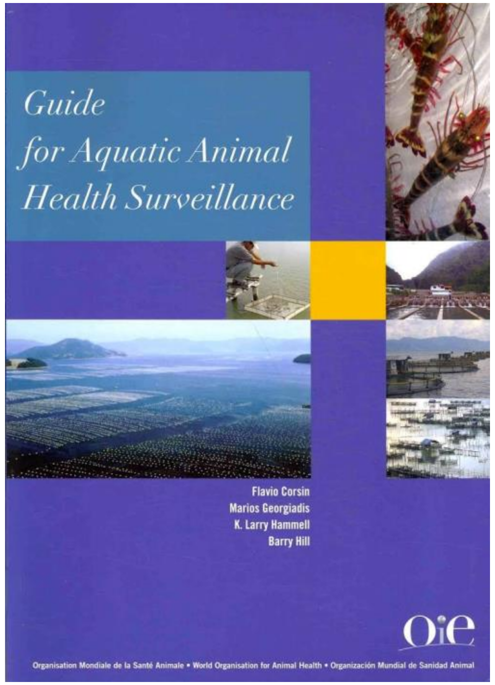
Epidemiology and surveillance

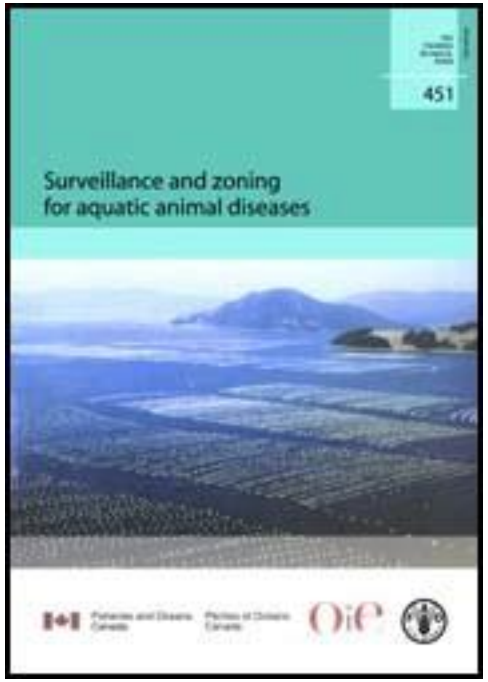
Principles of surveillance

Learning objectives

- Gain basic knowledge on surveillance systems
- Understanding the keys steps for setting up a surveillance system


OIE
WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future
Aquatic Animal
Health Code
2016


Guide
for Aquatic Animal
Health Surveillance
Flavio Corsin
Marios Georgiadis
K. Larry Hammell
Barry Hill
OIE
Organisation Mondiale de la Santé Animale • World Organisation for Animal Health • Organización Mundial de Sanidad Animal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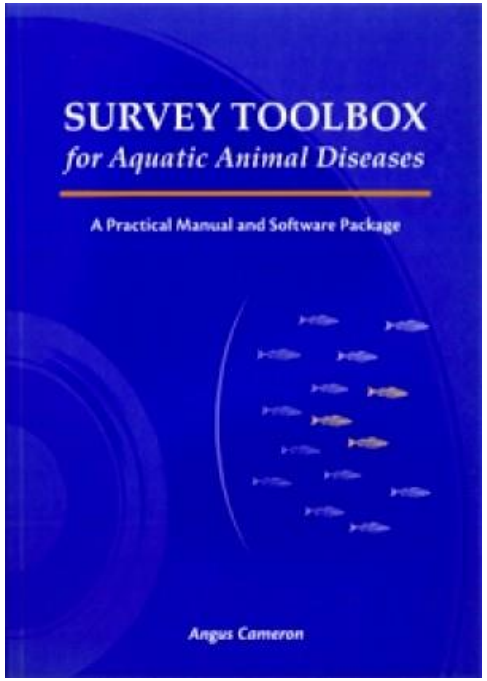
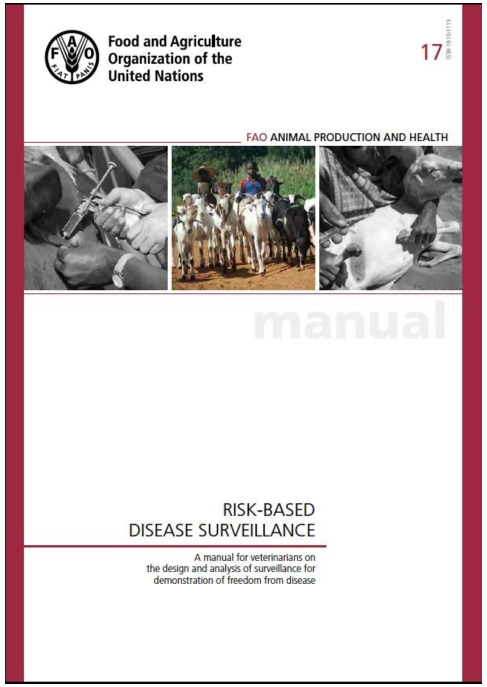
Surveillance and zoning
for aquatic animal diseases
OIE


SURVEY TOOLBOX
for Aquatic Animal Diseases
A Practical Manual and Software Package
Angus Cameron


Food and Agriculture
Organization of the
United Nations
17
FAO ANIMAL PRODUCTION AND HEALTH
manual
RISK-BASED
DISEASE SURVEILLANCE
A manual for veterinarians on
the design and analysis of surveillance for
demonstration of freedom from disease

What is surveillance?

- A planned, continuous activity for collecting, collating, analysing and disseminating disease and health data information from a defined population

- OIE International Aquatic Animal Health Code:

“the **systematic series of investigations** of a given population of aquatic animals to detect the occurrence of disease **for control purposes**, and which may involve testing samples of a population”

What is surveillance?

- A planned, continuous activity for collecting, collating, analysing and disseminating disease and health data information from a defined population

- FAO Surveillance and zoning for aquatic animal diseases:

“a **mechanism** applied to **collect and interpret data on the health of animal populations**, to accurately describe their health status with respect to specific diseases of concern”.

Survey vs monitoring

- Survey
  - The structured collection of health information from a specified population
  - Targets only specific health problems -> can supplement surveillance.
  - A single survey rarely provides sufficient evidence for disease status
- Monitoring
  - The systematic series of investigation of a given population of aquatic animals
  - May involve testing samples of a population
  - E.g. to detect
    - Changes in the prevalence
    - Changes in geographical distribution of disease
    - Emerging diseases

What is the overall purpose of surveillance?

- To inform stakeholders and assist in decision-making on the planning and implementation of control measures
  - Trade
  - Support safe movement at farm, zone or national level
  - Eradication
  - Prioritization of resources
  - Socio-economic impact
  - ……..
- Should be cost-efficient!

Objectives of surveillance

- Objectives defined to achieve the purpose
  - Substantiate claims of absence of infection (or disease)
  - Detect emerging (exotic) disease
  - Monitor endemic diseases (distribution, prevalence, incidence)
  - Monitor the success of intervention (e.g. eradication)
- Must be clearly stated to help surveillance system design
  - Consistency with disease situation
  - Recognition of stakeholders needs
  - Types of surveillance system

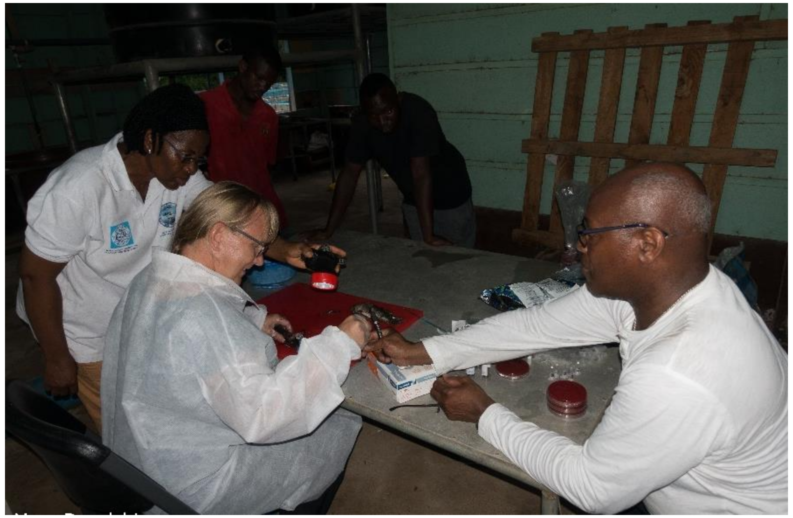
Stakeholders

- Surveillance => a multifaceted activity => many potential stakeholders
  - Competent authority
  - Industry (aquaculture, service)
  - Consumers
  - Wildlife (organizations, public)
  - Trading partners
  - Decision makers

- Who will benefit?
- How will results be disseminated/communicated?

Various surveillance approaches

- **Passive surveillance**
- **Active surveillance** (Targeted surveillance)
- **Risk-based surveillance**
- Sentinel surveillance
- Syndromic surveillance
- Proxy surveillance
- Post-harvest processing
- …and more



Passive surveillance

- Not targeted for a specific disease
  - Notifications by farmers
  - Routine diagnostic samples
- Will mainly detect disease (rather than infection only)
  - Non-requested agent investigation based on history and other laboratory findings
- Usually underestimates the prevalence of disease
- Recommended by the OIE as a first step in the surveillance effort

Active surveillance

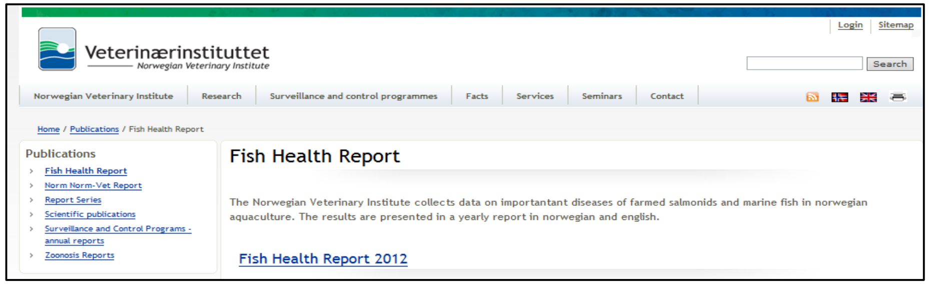
- Specifically designed sampling of a defined population
- Can achieve a “reasonably high” confidence level
- Can be designed to identify infection or disease
- Usually very resource intensive
  - People
  - Laboratory
  - Money

Risk-based surveillance

- Most commonly recommended surveillance design (e.g. the EU)
- Aims to increase the cost-efficiency
  - Disease probability
  - Severity of consequences of disease
- Several areas of inclusion, e.g.
  - Populations
  - Sample size calculation
  - Data analyses
  - Data interpretation

Agent/disease information

- Aetiological agent/disease
- Case definition
- Clinical signs
- Epidemiology – e.g. transmission routes
- Diagnostics – availability, validity



Population definitions (1)

- Population of interest
  - aim to get a representative sampling of this susceptible population
  - -> affects agent entry, agent spread and likelihood of agent/disease detection
    - Population structure (demography)
    - Locations
    - Disease histories
    - Exposure
    - Susceptibility

Population definitions (2)

- Population of interest

⬇

- Target population
  - population to which the conclusions (absence/presence) will be applied

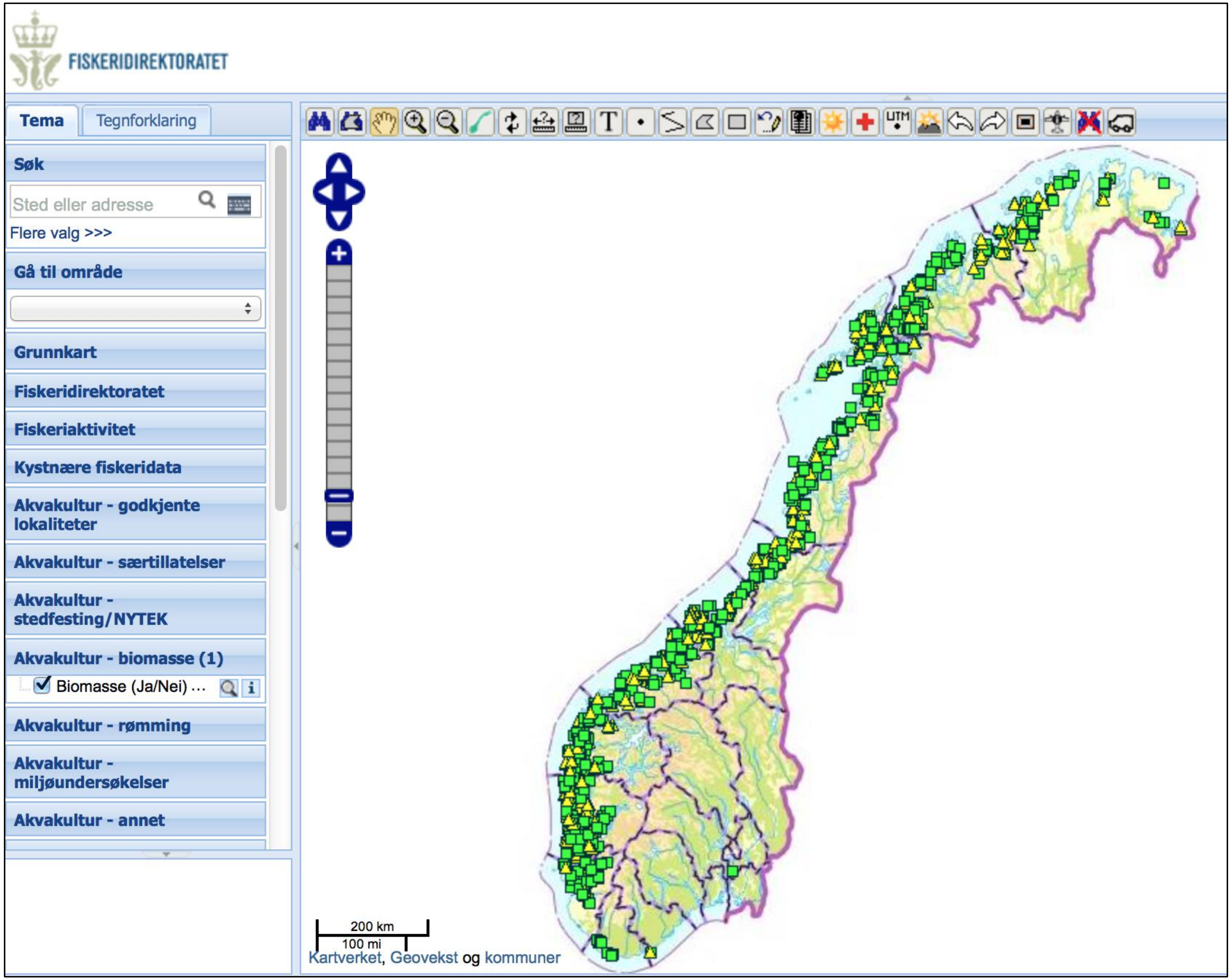
⬇

- Study population
  - population from which the surveillance data are gathered
  - May = target population or be a subset of it

Epidemiological unit

In the context of surveillance:

- = units selected when sampling
- E.g. animals, ponds/cages, <u>farms</u>, villages, districts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Grunnkart
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Fiskeriaktivitet
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Akvakultur - særtillatelser
Akvakultur - stedfesting/NYTEK
Akvakultur - biomasse (1)
Biomasse (Ja/Nei) ...
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Akvakultur - miljøundersøkelser
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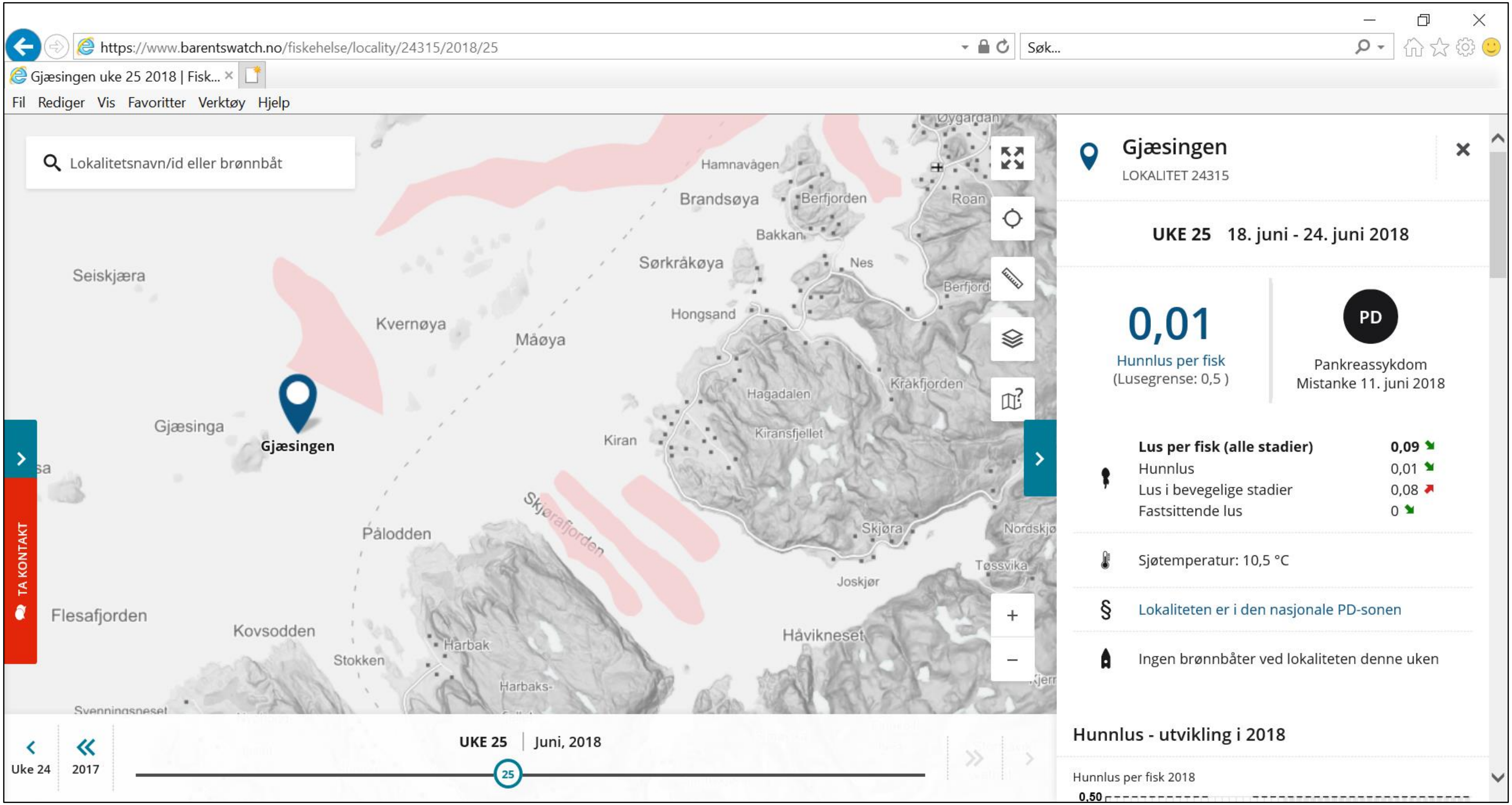
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Brandsøya
Berfjorden
Bakkan
Sørkråkøya
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Lus i bevegelige stadier 0,08
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Hunnlus per fisk 2018
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CHAPTER 2.3.6.

INFECTION WITH SALMONID ALPHAVIRUS

1. Scope[1]

For the purpose of this chapter, infection with salmonid alphavirus (SAV) means infection with any subtype of SAV of the genus *Alphavirus* of the family *Togaviridae*.

Infection with SAV may cause pancreas disease (PD) or sleeping disease (SD) in Atlantic salmon (*Salmo salar* L.), rainbow trout (*Oncorhynchus mykiss*) and brown trout (*Salmo trutta* L.) (Boucher et al., 1995; McLoughlin & Graham, 2007). The virus is horizontally transmitted, and the main reservoirs of SAV are clinically diseased or covertly infected fish (Viljugrein et al., 2009). The disease is a systemic disease characterised microscopically by necrosis and loss of exocrine pancreatic tissue, and heart and skeletal muscle changes. The mortality varies significantly, from negligible to over 50% in severe cases, and up to 15% of surviving fish will develop into long, slender fish ('runts') (McLoughlin & Graham, 2007).

2. Disease information

2.1. Agent factors

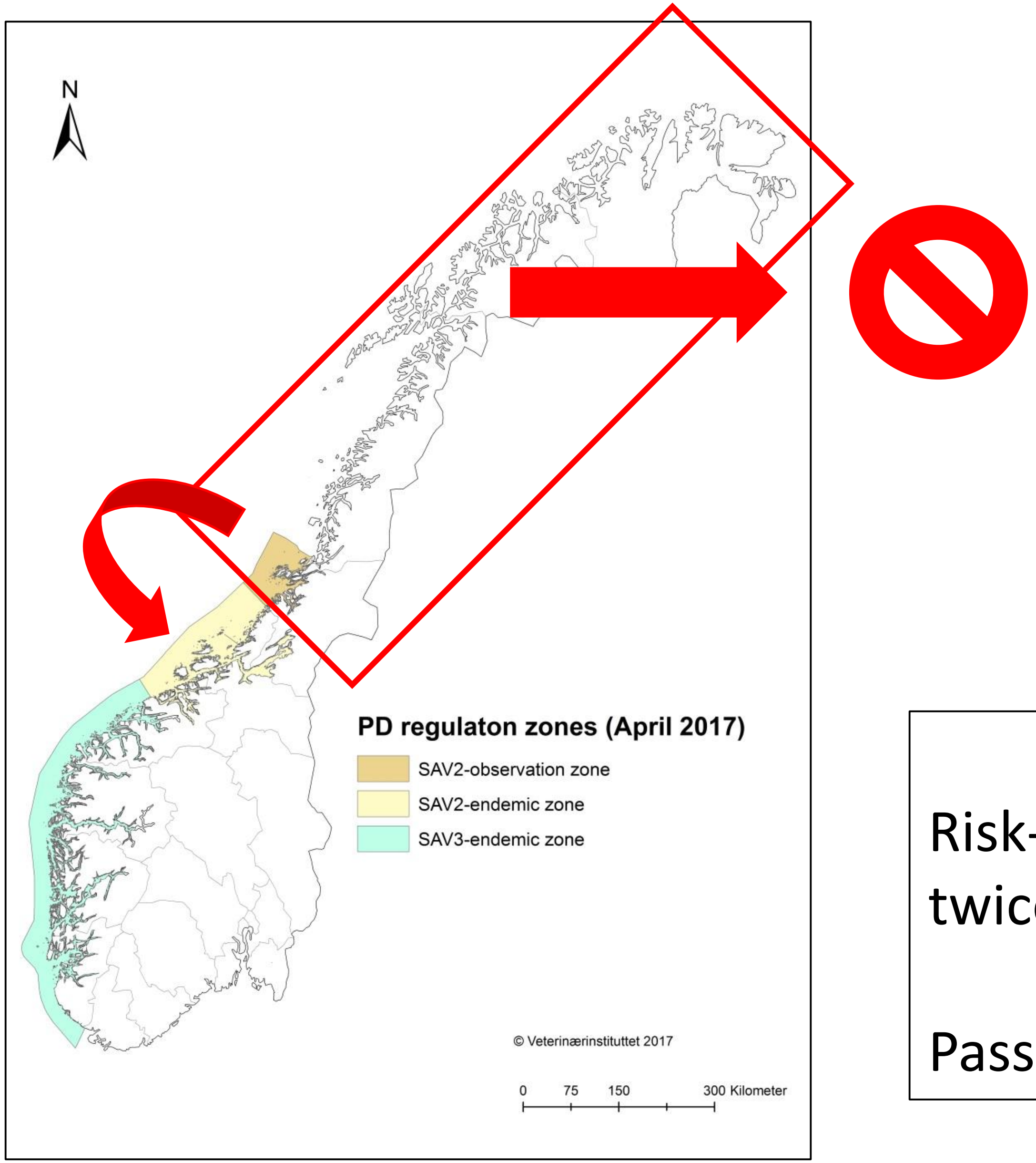
2.1.1. Aetiological agent, agent strains

Northern zone:

tested negative for 2 consecutive years

=>

free status application

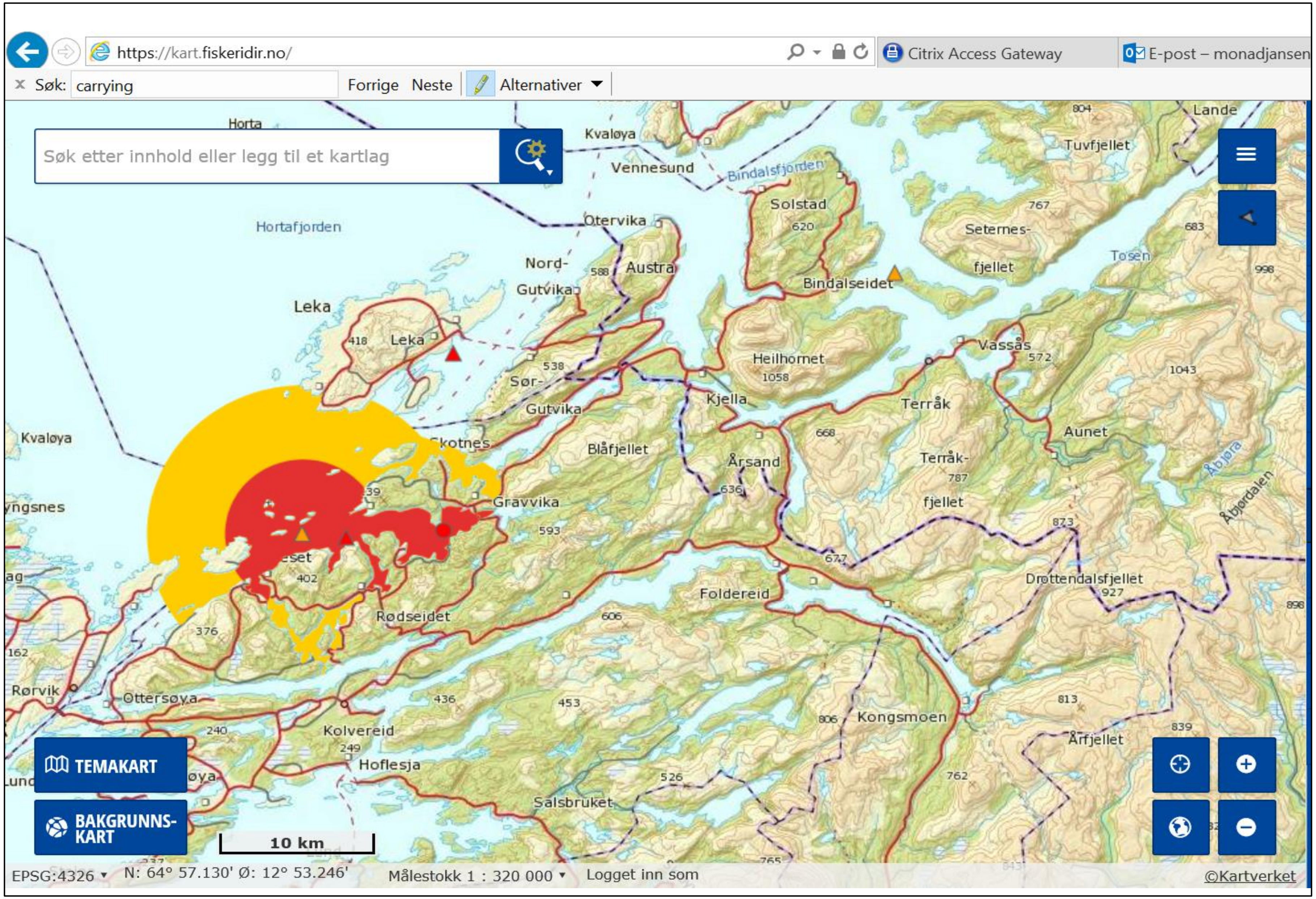


All sites:

Risk-based sampling twice/year

+

Passive surveillance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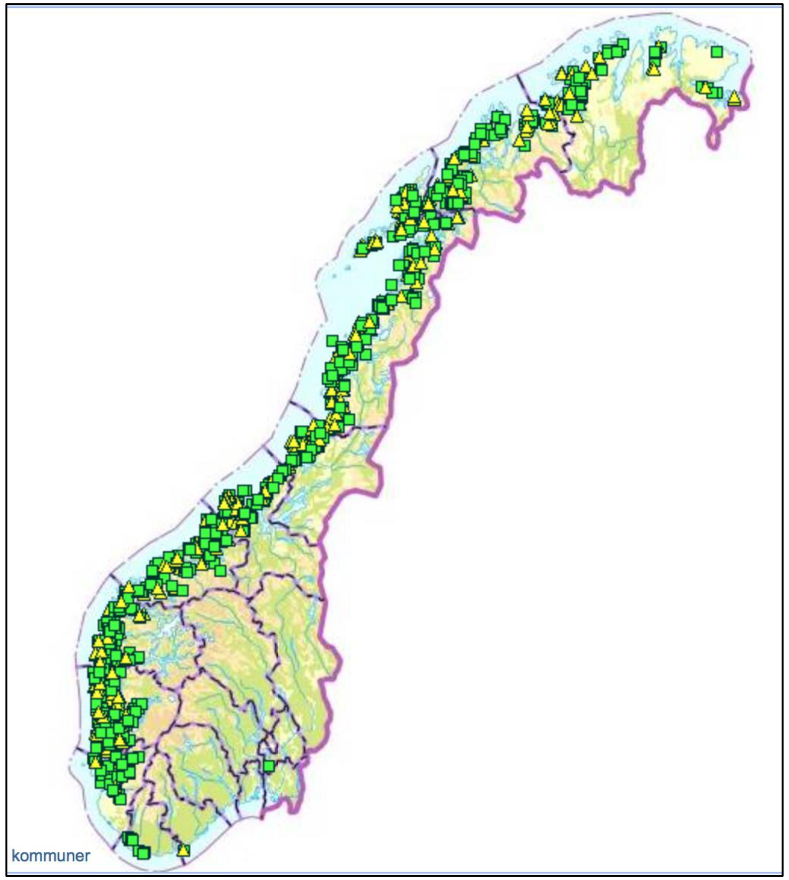
New surveillance system



- All sites
- Risk-based

Main purpose:

- Improved overview
- Trade

Industry bears the cost!

Sampling issues (1)

- For surveillance in the aquaculture industry we commonly need to be able to select:
  - Fish farms - within country/zone
  - Fish within farms

- Need to determine a sample size to (randomly) sample enough farms and fish to optimize your estimate
  - not too many –> waste of resources
  - not too few –> won’t give you the results you want

Sampling issues (2)

- Is there access to individuals that are representative of the population?
  - Random samples are rarely possible in fish farms
    - Dead, sick, moribund, apparently healthy, healthy
    - Different ease of sampling
  - Fully representative samples are rarely achieved

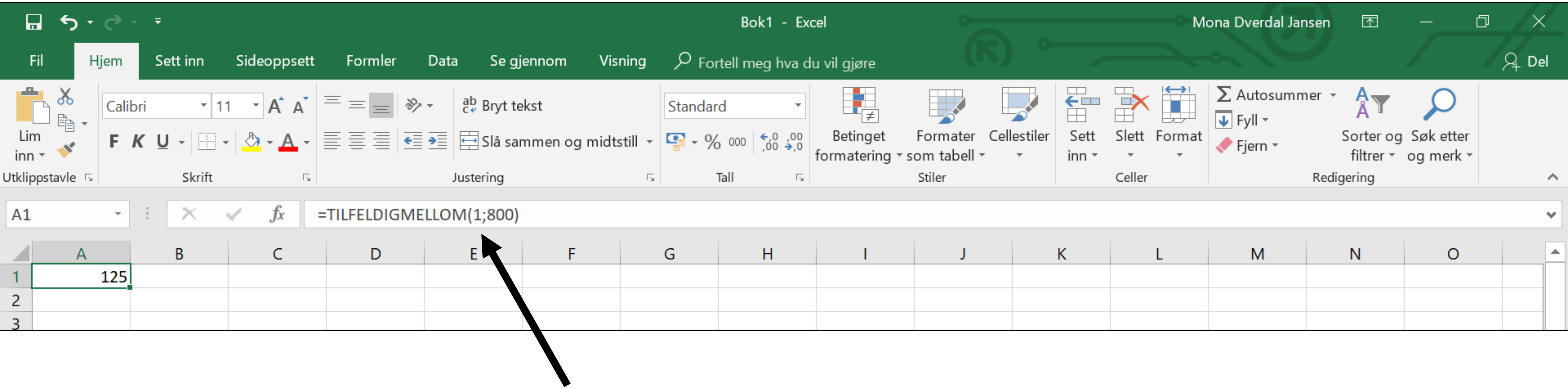
How to sample?

- Several methods available:
  - Non-probability sampling (not random, e.g. convenience - only cooperating farmers)
  - Simple random sampling
  - Systematic random sampling
  - Stratified random sampling (random sampling within groups)
  - ………….

Simple random sampling

- Sampling from a population (e.g. farms) that is homogeneous in relation to disease distribution
- Requires a sampling frame
  - complete list of all sampling units available in the source population
  - requires individual identification for each sampling unit
- Each individual is selected using a random process so that each has a equal chance to be selected
- Collect the units with ID indicated by the random process

Random number generator



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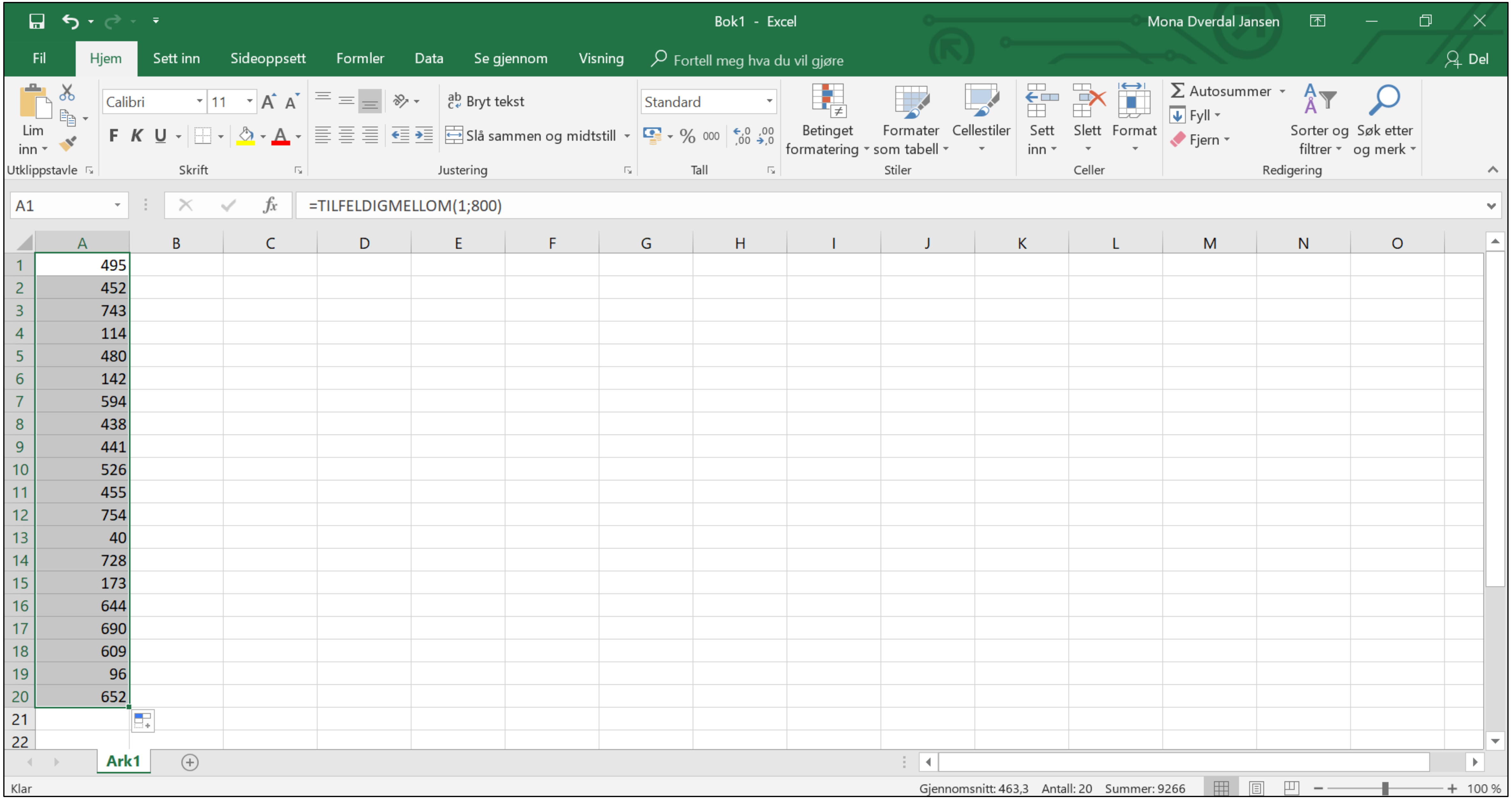
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Antall: 20
Summer: 9266
100 %

Systematic random sampling

- Sampling from a population that is homogeneous in relation to disease distribution
- Units are sampled at a regular interval after a random start
  - No need for a sampling frame
- All units have to be sequentially accessible and each unit has an equal chance of being selected
  - Farms
  - Fish e.g. at slaughter, during vaccination
- Subject to bias in the random start, the interval or in the listing order

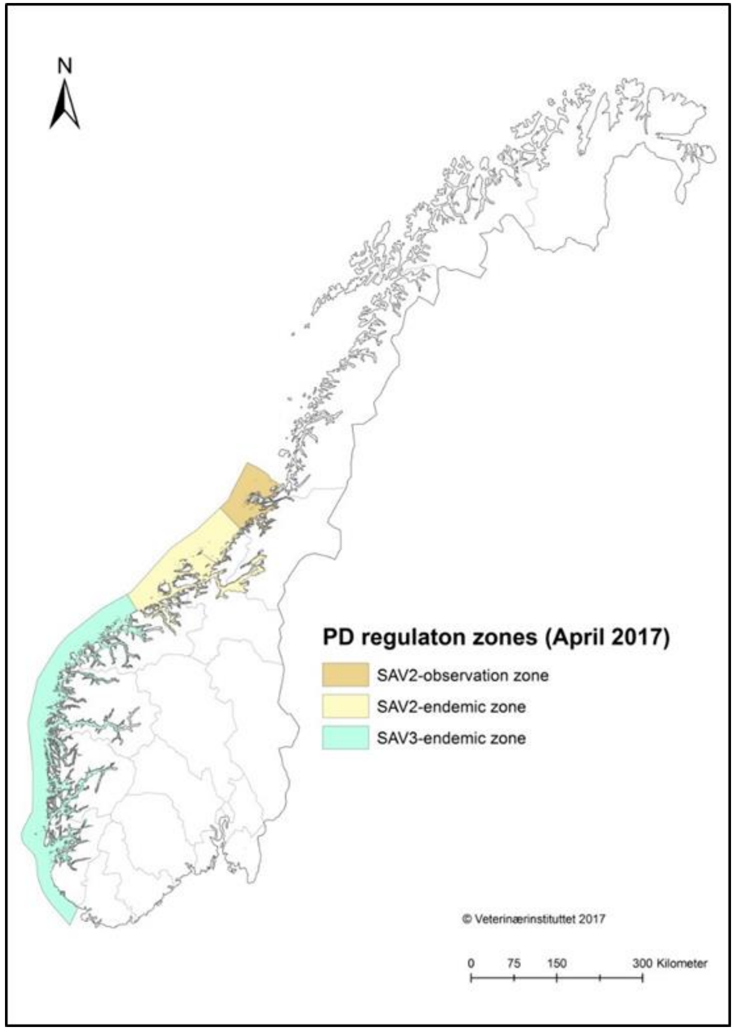
Systematic random sampling - example

1. Calculate the Interval j = Total number of animals / Sample size
   - We want 100 samples from 10 000 fish unit
   - j = 10 000/100 = 100

2. Randomly pick a number from within j
   - Starting with random in first 1-100 e.g. 27

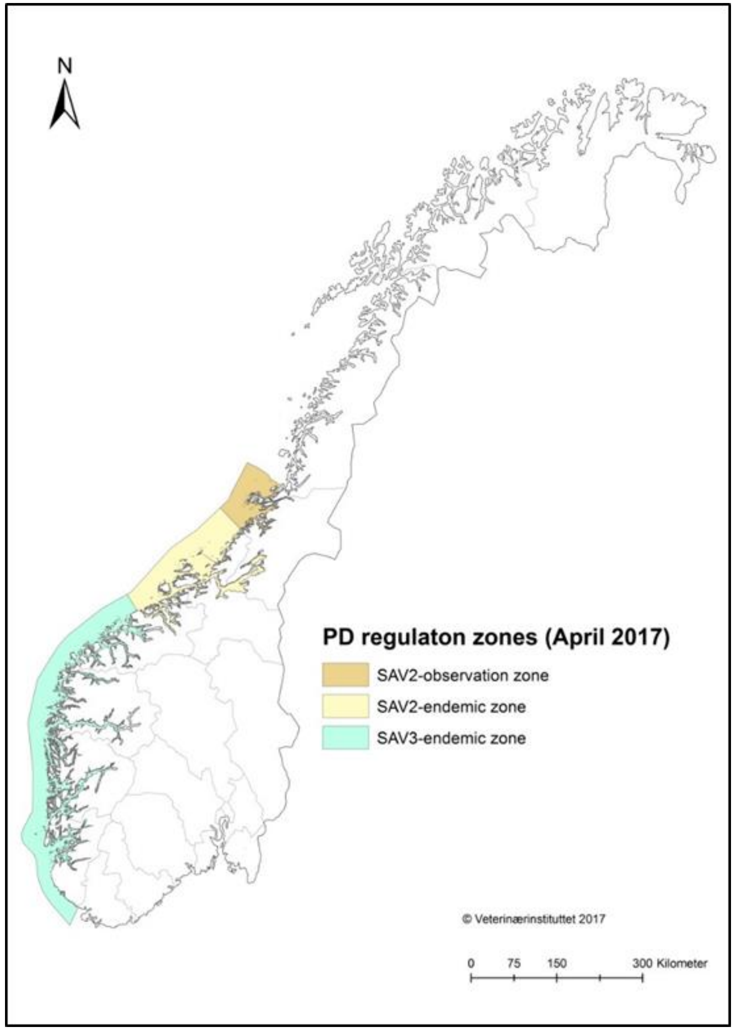
3. Sample every j^{th} animal
   - E.g. 27, 127, 227,….., 9 927

Stratified random sampling



- Sampling from a population that is heterogeneous regarding the disease distribution
- The population can be categorized into groups where the units are more homogeneous than between than between groups

Stratified random sampling



- Separate all units into mutually exclusive strata -> no overlap between them
  - Units within each stratum are assumed to be homogeneous in the disease distribution
- Include all strata
- Within each stratum, randomly select units (simple random or systematic random)
  - The same number of units in each strata

  or

  - **A proportionate sample to the number of units in each stratum**

Now we know how we want to sample….

……… how many should be included?

- How many farms?
- How many fish?

Sample size – general considerations

- Rarely possible to measure the entire population
- -> Parameters of interest calculated from subset of population
- Important to have enough samples to have sufficient certainty to aid decision-making
- Almost always restricted by the available budget

Sample size – common approache

- Need to get sufficient sensitivity at farm level (or other unit-level)
  - Enough fish at each site

- Often result in:
  - Calculation of the cost per site
  - This then determines the maximum number of sites that can be sampled

Sample size determination

Key inputs

1. Design prevalence
   - expected prevalence of infection in the sampled group (e.g. moribunds)
2. Confidence level required for the result
   - typically use 95% (99% if aim at higher certainty)
3. Sensitivity of the test used
   - Usually assume perfect specificity
4. Population size
   - E.g. number of farms, number of fish

Design prevalence

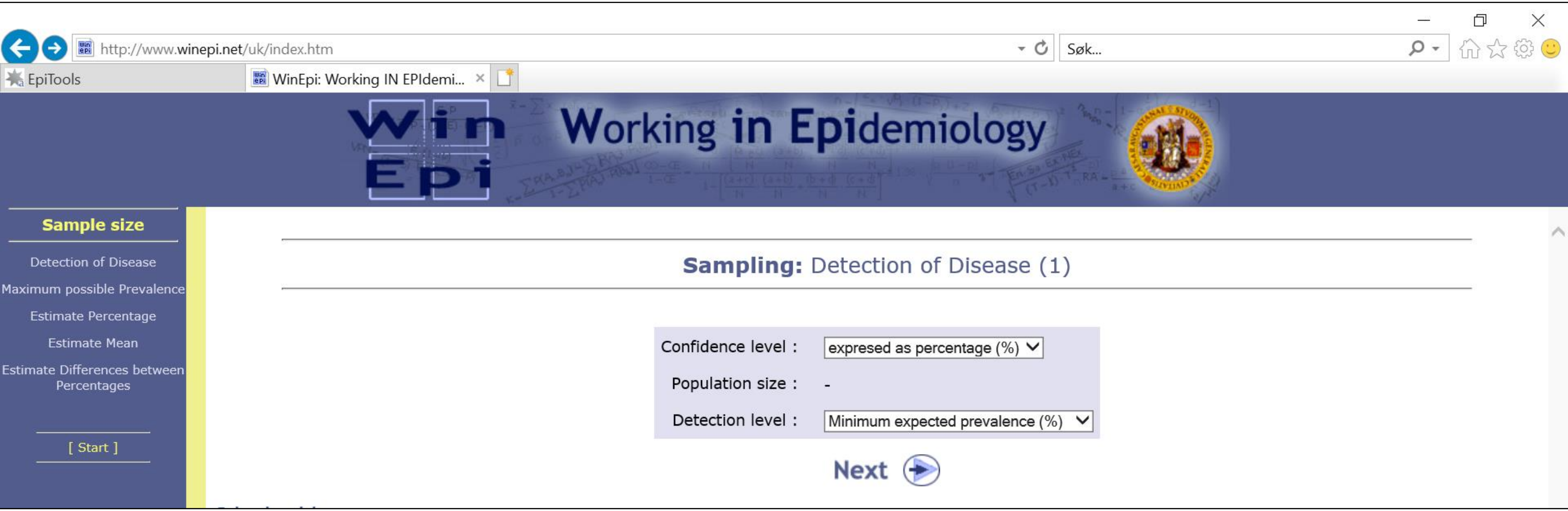
- Minumum expected prevalence of infection in the study population
  - Dynamics of infection for the agent in question
- How to determine the value?
  - **Between 1% and 5%** if only a small proportion of the population is expected to be infected (e.g. early in the outbreak)
  - **>5%** if expecting high prevalence (**10%** - often used with risk-based sampling)
  - **2%** = standard if no reliable information is available
  - (Where available: see relevant disease chapter of the OIE Aquatic Manual)

Sample size calculation

Use

- Free software available at:
  - http://www.winepi.net/uk/index.htm
  - http://epitools.ausvet.com.au/content.php?page=home

- Published tables and equations in epidemiology text books, manuals



"Population" can be the country's tilapia farms, the fish in a farm and so on

Working in Epidemiology

Sampling: Detection of Disease (2)

Confidence level % :	95
Population size :	40000
Minimum expected prevalence (%) :	10

Working in Epidemiology

Sampling: Detection of Disease (3)

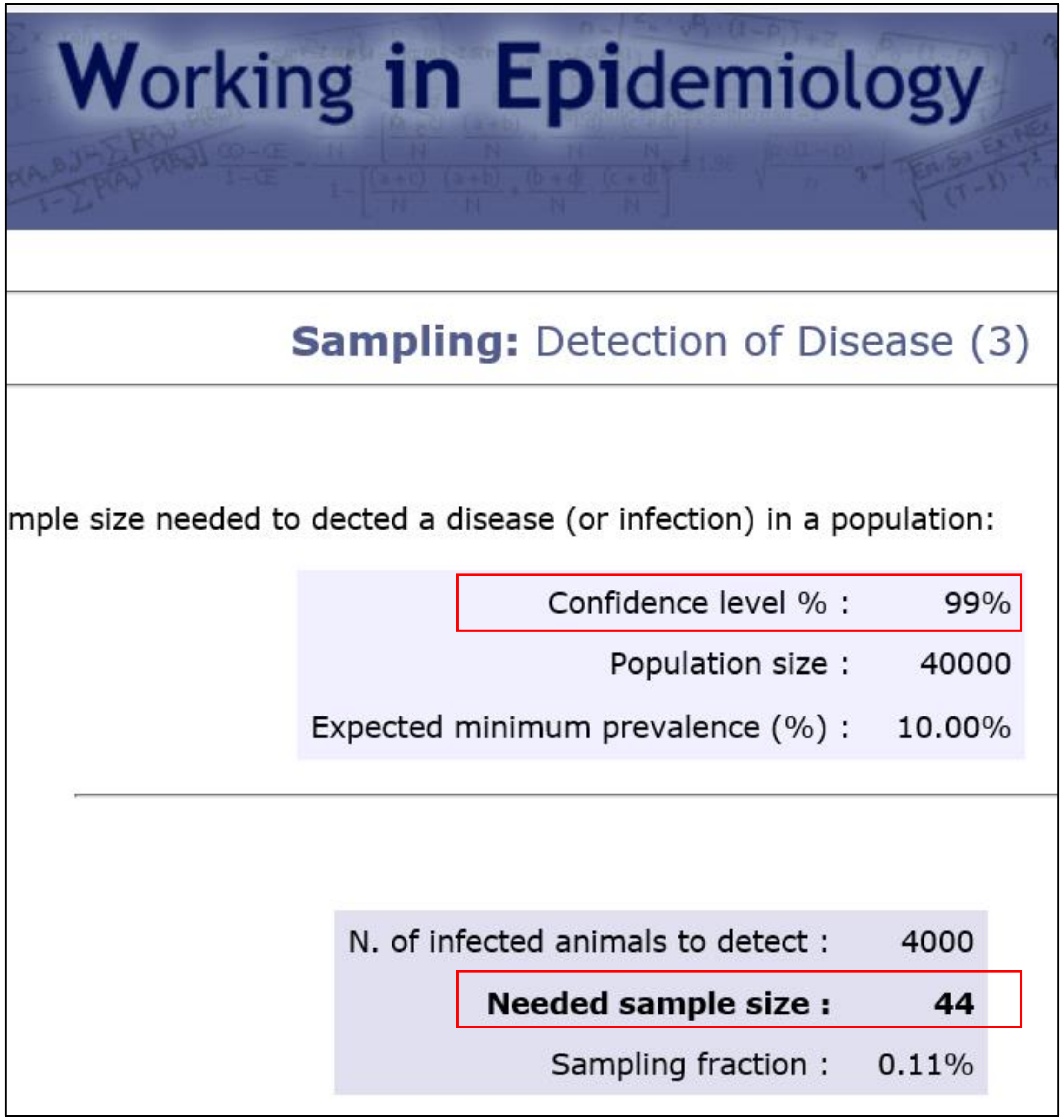
mple size needed to dected a disease (or infection) in a population:

Confidence level % :	95%
Population size :	40000
Expected minimum prevalence (%) :	10.00%

N. of infected animals to detect :	4000
Needed sample size :	**29**
Sampling fraction :	0.07%

Assuming perfect Se & Sp

Risk-based sampling



Assuming perfect Se & Sp

Risk-based sampling

Working in Epidemiology

Sampling: Detection of Disease (3)

ample size needed to dected a disease (or infection) in a population:

Confidence level % :	95%
Population size :	40000
Expected minimum prevalence (%) :	5.00%

N. of infected animals to detect :	2000
Needed sample size :	**59**
Sampling fraction :	0.15%

Assuming perfect Se & Sp

Risk-based sampling

What about wild fish populations?

- More difficult due to many unknowns
  - Best available information to estimate population size
  - Is it possible to get risk-based samples?
  - If not, random sampling or systematic random sampling of caught fish
  - Harder to define design prevalence so use a conservative estimate

Working in Epidemiology

Sampling: Detection of Disease (3)

mple size needed to dected a disease (or infection) in a population:

Confidence level % :	95%
Population size :	40000
Expected minimum prevalence (%) :	1.00%

N. of infected animals to detect :	400
Needed sample size :	**297**
Sampling fraction :	0.74%

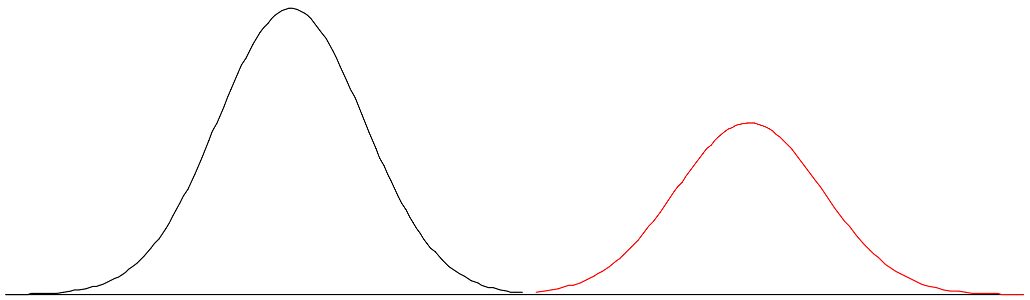
Assuming perfect Se & Sp

Risk-based sampling possible?

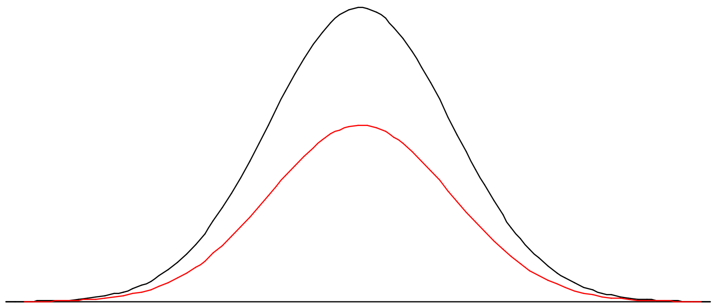
Large effect of a low design prevalence!

Diagnostic tests

The ability of the test to distinguish between diseased and non-diseased

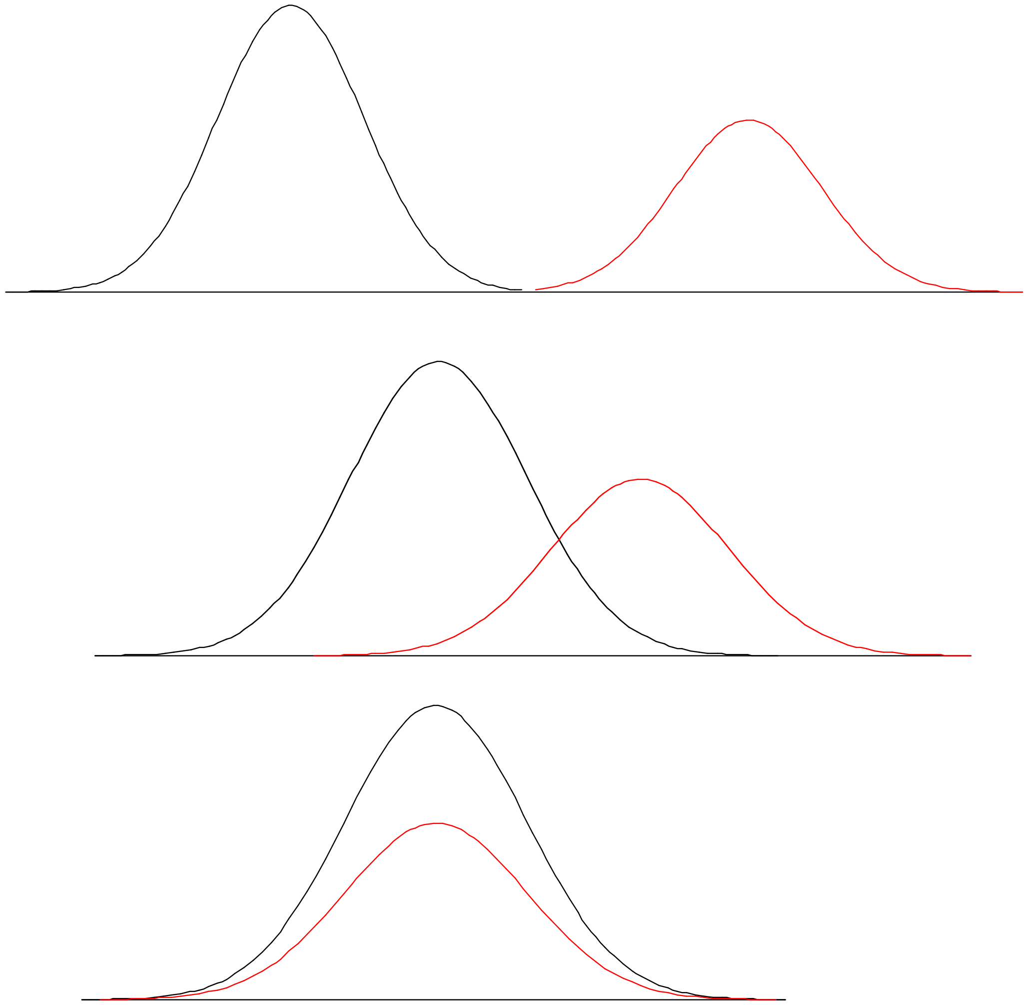


Perfect test
(no tests are perfect)



Useless

The ability of the test to distinguish between diseased and non-diseased

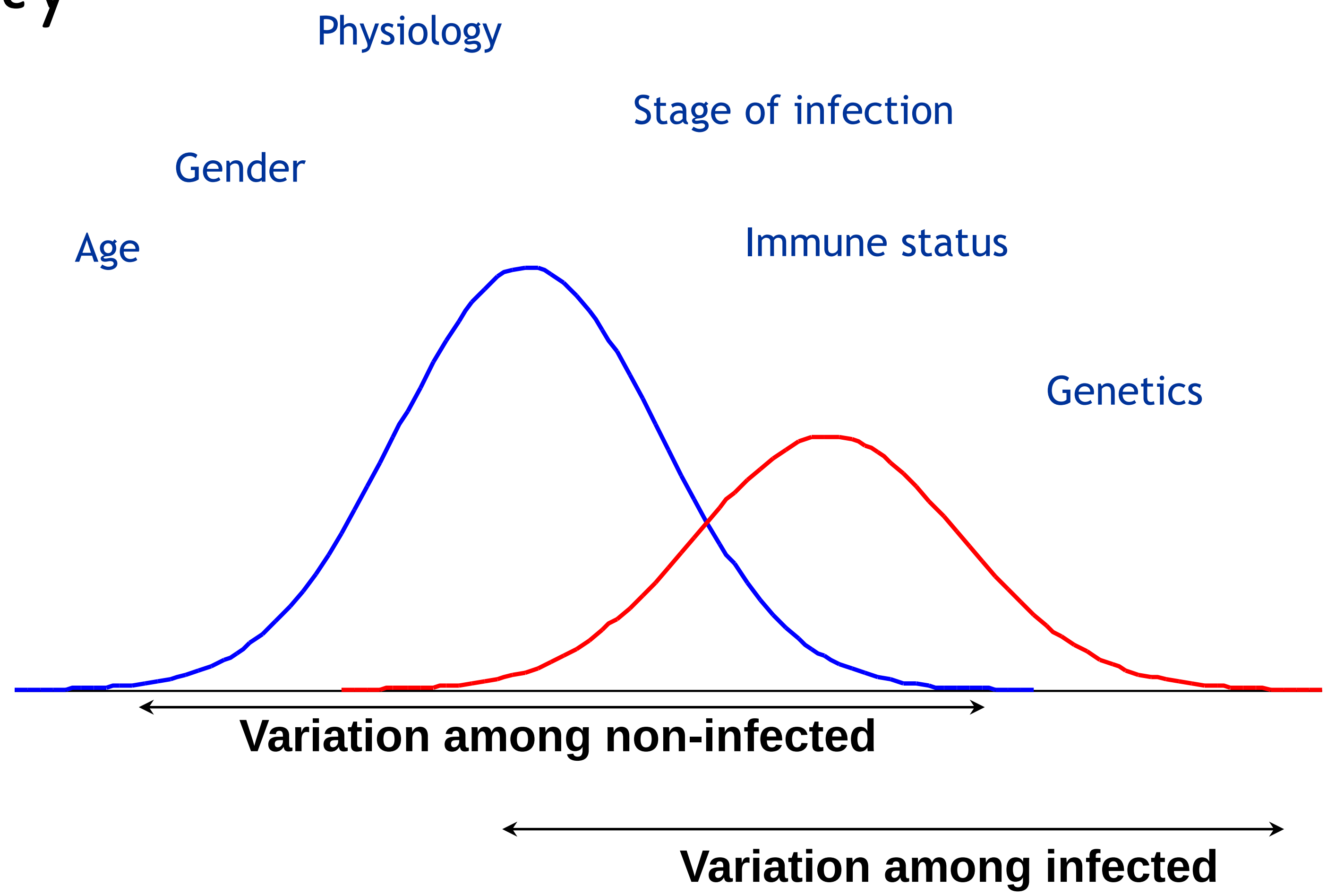


Perfect test
(no tests are perfect)

Normal situation

Useless

Variability



Variability

- Biological variation
    - age, stage of infection, immune status, physical condition,…

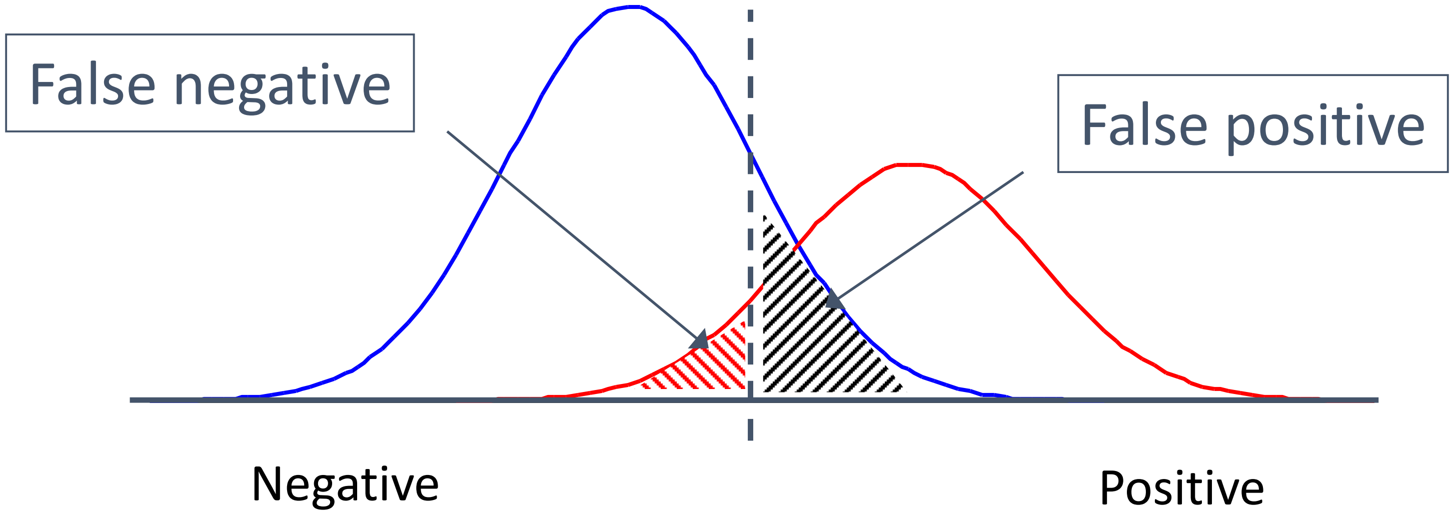
- Variation due to differences in case definition
    - e.g. Histopathology vs PCR

- Technical variation
    - within lab variability (repeatability)
    - between lab variability (reproducibility)

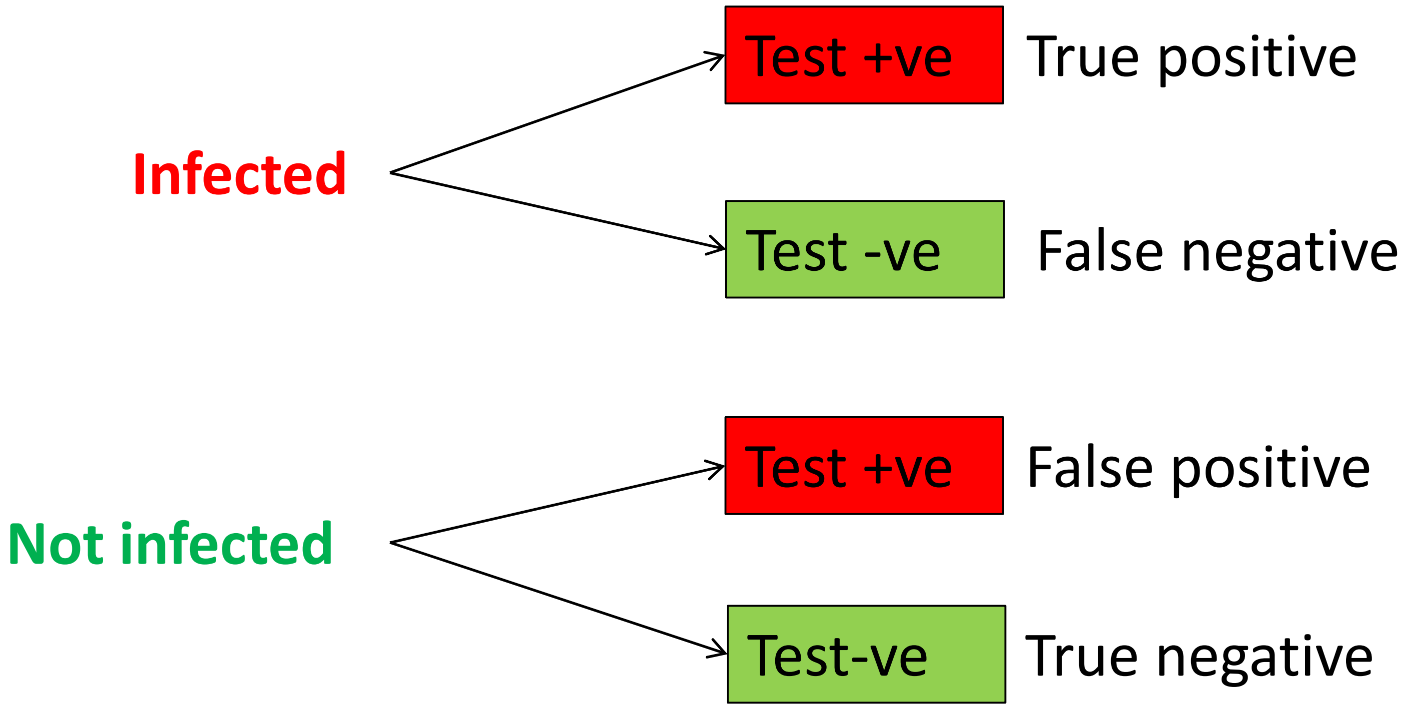
Some consequences of variability

- Different individuals or populations with same status can give a different response
- Overlap in the distributions will usually occur
  - Due to overlap in distributions and means
- Need of “Cut-off values” : False positive – false negative

False positives and falses negatives



Binary test output – no/yes; 0/1



Sensitivity and specificity

	True disease status		
	D+	D-	
Test +			
Test -			

Sensitivity and specificity

	D+	D-	
Test +	a	b	g = a + b
Test -	c	d	h = c + d
	a + c	b + d	g+h

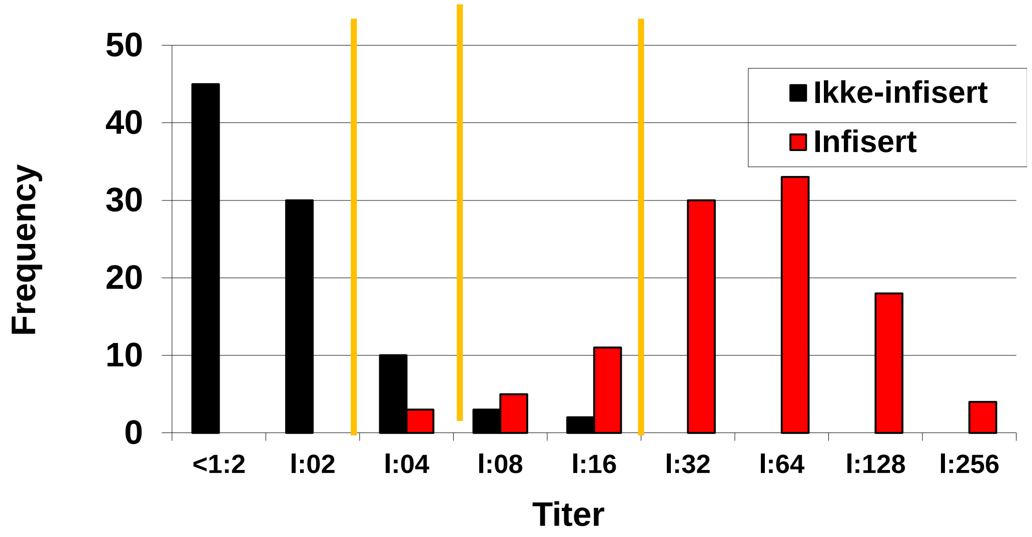
Se= a/a+c

Sp= d/b+d

Sensitivity (Se): probability of testing positive if truly infected

Specificity (Sp): probability of testing negative if truly non-infected

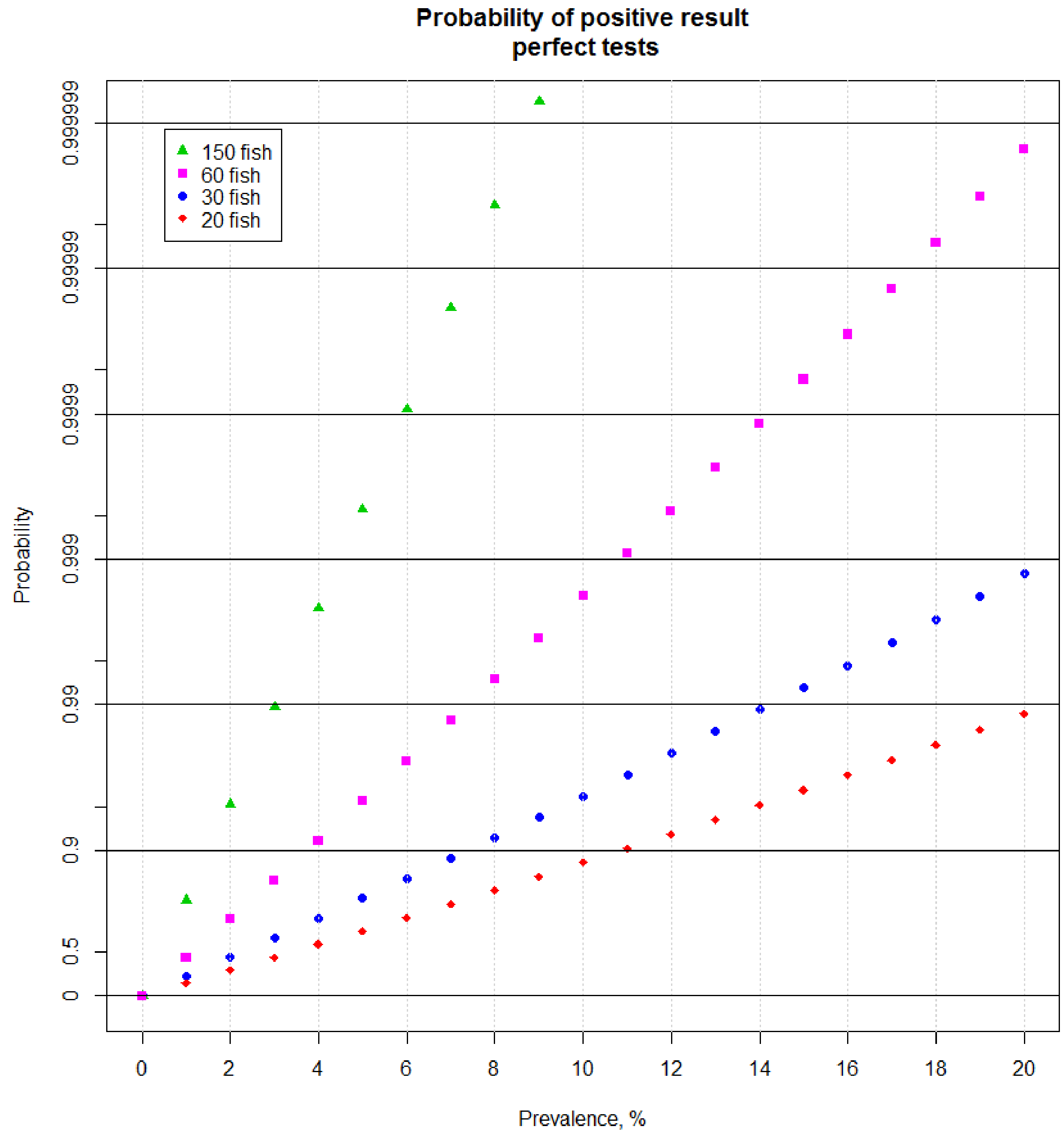
Sensitivity and spesificity



Cut-off
>=1:4

	D+	D-
Test +	104	15
Test -	0	75

Se = 104/104 = 1
Sp = 75/90 = 0,83



Source: Norwegian Veterinary Institute

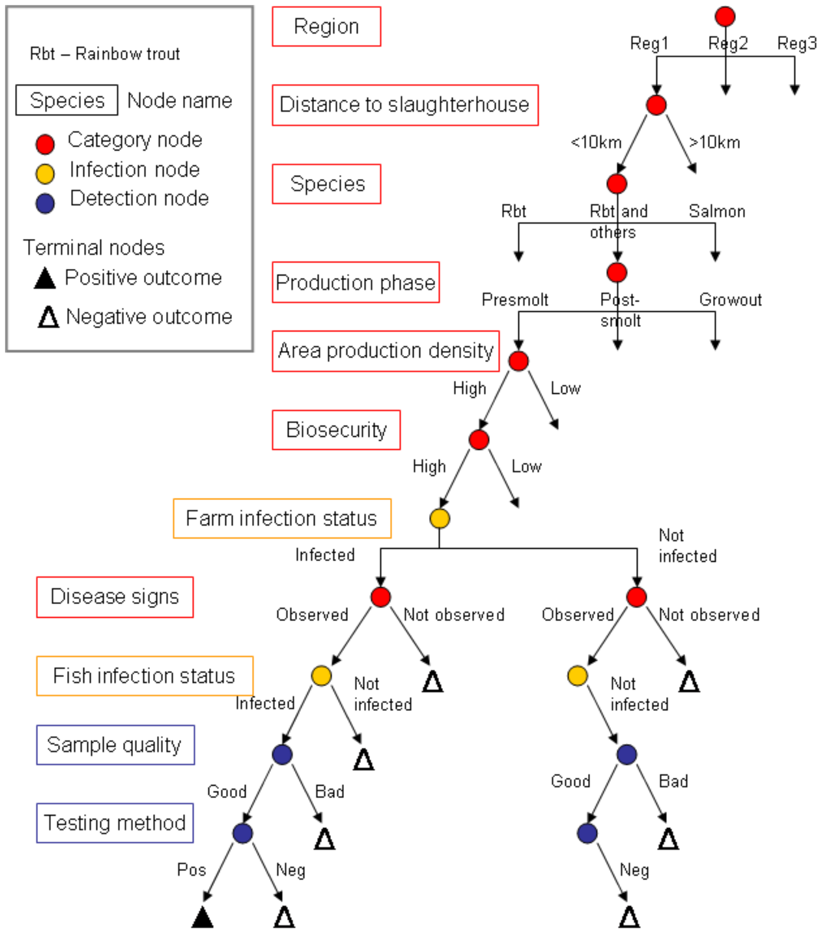
Aspects to be considered when interpreting diagnostic test results

- Pooling of samples
  - How does that affect the Se (/Sp)?
- When utilizing several tests
  - How to combine the results?
  - How does this affect the Se (/Sp)?
- Aggregate testing
  - Testing several individual animals in order to classify herds
  - How does that affect the Se (/Sp)?

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false positives if the population is free
2	100	100	149	0
2	100	99	524	9
2	100	95	1,671	98
2	99	100	150	0
2	99	99	528	9
2	99	95	1,707	100
2	95	100	157	0
2	95	99	542	9
2	95	95	1,854	108
2	90	100	165	0
2	90	99	607	10
2	90	95	2,059	119
2	80	100	186	0
2	80	99	750	12
2	80	95	2,599	148
5	100	100	59	0
5	100	99	128	3
5	100	95	330	23
5	99	100	59	0
5	99	99	129	3
5	99	95	331	23
5	95	100	62	0
5	95	99	134	3
5	95	95	351	24
5	90	100	66	0
5	90	99	166	4
5	90	95	398	27
5	80	100	74	0
5	80	99	183	4
5	80	95	486	32
10	100	100	29	0
10	100	99	56	2
10	100	95	105	9
10	99	100	29	0
10	99	99	57	2
10	99	95	106	9
10	95	100	30	0
10	95	99	59	2
10	95	95	109	9
10	90	100	32	0
10	90	99	62	2
10	90	95	123	10
10	80	100	36	0
10	80	99	69	2
10	80	95	152	12

Source: OIE Guide for Aquatic Animal Surveillance (p. 34)

Surveillance system sensitivity



Lyngstad *et al* (2016) Preventive Veterinary Medicine, 124, 85-95 http://epitools.ausvet.com.au/content.php?page=home

Epi Tools - EpiTools epidemi...

ausvet

EpiTools epidemiological calculators

Home | Prevalence | Freedom | Studies | Diagnostics | Sampling | English

EpiTools epidemiological calculators

This site is developed and maintained by Ausvet. The site is intended for use by epidemiologists and researchers involved in estimating disease prevalence or demonstrating freedom from disease through structured surveys, or in other epidemiological applications.

Surveillance utilities

- **1-Stage representative freedom surveys**
- **2-Stage representative freedom surveys**
- **Risk-based freedom surveys**
- **Random Sampling from a population**
- **Estimating true prevalence**
- **Pooled prevalence calculator**
- **Survey Toolbox for livestock diseases and freedom in finite populations**
- **HerdPlus module for herd-sensitivity and freedom in finite populations**

Epidemiological studies

- **Sample size calculations**
- **Summarise categorical or continuous data**
- **Statistical significance testing**
- **Probability distributions**
- **Bioequivalence analysis**

Diagnostic tests

- **Application of diagnostic tests**

Case study data

- **GIS case study data from *Epidemiology for Field Veterinarians* text**
- ***Epidemiological Problem Solving* case studies and model answers**

Suggested citation: Sergeant, ESG, 2018. Epitools epidemiological calculators. Ausvet Pty Ltd. Available at: http://epitools.ausvet.com.au.

http://epitools.ausvet.com.au/content.php?page=RiskBasedSSSimple_1

http://epitools.ausvet.com.au/content.php?page=RiskBasedSeSimple&RelRisk=2&PPr=0.1&PStar=0.05&Se=0.95&nH=30&nL=0&prior=0.5

Søk...

Epi Tools - Simple risk-based...

ausvet

EpiTools epidemiological calculators

Home | Prevalence | Freedom | Studies | Diagnostics | Sampling | English

FreeCalc
Risk based 1-stage
Representative 1-stage
Representative 2-stage

Sample Size - single level
Sample Size - single level
Sensitivity - single level
Sensitivity - single level

Simple risk-based s… n of surveillance sensitivity

Input Values

Relative risk :	2
Population proportion in high risk group :	0.1
Design prevalence :	0.05
Test sensitivity :	0.95
Number of high-risk units sampled	30
Number of low-risk units sampled	0

T… y for simple risk-based surveillance, for instance, a survey in which a high risk population is targeted.

This analysis assumes … ng of disease (for instance, we are working at the herd level), and that the effective specificity of the surveillance system is e… es are followed up to ensure that they are not false positives).

One risk factor is consid… lowing information is required:

- The relative risk: this measures the risk of animals being infected in the high-risk group, relative to the risk of animals being infected in the low-risk group. For risk-based surveillance, this should be greater than 1. If analysing biased surveillance (for instance abattoir testing), the animals tested may have *lower* probability of being infected than the rest of the population.
- The population proportion: this is the proportion of animals from the entire population that are in the high-risk group.

In addition, the following parameters are required:

- The design prevalence: this is the assumed prevalence of disease, if the disease is present in the population. It is used as a standard by which the sensitivity of the surveillance can be evaluated.
- The individual animal test sensitivity: this is the sensitivity of the test performed on individual animals.
- The number of animals tested in each of the high and low risk groups.
- The prior confidence of freedom before the surveillance was undertaken. This is combined with System sensitivity to calculate posterior confidence of freedom.

The results include:

- the sensitivity of the surveillance system, or in other words, the probability that the surveillance system would detect at least one infected animal … was present at the specified design prevalence.

http://epitools.ausvet.com.au/content.php?page=RiskBasedSeSimple http://epitools.ausvet.com.au/content.php?page=RiskBasedSeSimple&RelRisk=2&PPr=0.1&PStar=0.05&Se=0.95&nH=25&nL=5&prior=0.5

Epi Tools - Simple risk-based...

Simple risk-based surveillance - calculation of surveillance sensitivity

Input Values

Relative risk : 2

Population proportion in high risk group : 0.1

Design prevalence : 0.05

Test sensitivity : 0.95

Number of high-risk units sampled 25

Number of low-risk units sampled 5

Prior confidence of freedom : 0.5

Submit

This page calculates the surveillance sensitivity for simple risk-based surveillance, for instance, a survey in which a high risk population is targeted.

This analysis assumes that there is no clustering of disease (for instance, we are working at the herd level), and that the effective specificity of the surveillance system is equal to one (all positives are followed up to ensure that they are not false positives).

One risk factor is considered, for which the following information is required:

- The relative risk: this measures the risk of animals being infected in the high-risk group, relative to the risk of animals being infected in the low-risk group. For risk-based surveillance, this should be greater than 1. If analysing biased surveillance (for instance abattoir testing), the animals tested may have *lower* probability of being infected than the rest of the population.
- The population proportion: this is the proportion of animals from the entire population that are in the high-risk group.

In addition, the following parameters are required:

- The design prevalence: this is the assumed prevalence of disease, if the disease is present in the population. It is used as a standard by which the sensitivity of the surveillance can be evaluated.
- The individual animal test sensitivity: this is the sensitivity of the test performed on individual animals.
- The number of animals tested in each of the high and low risk groups.
- The prior confidence of freedom before the surveillance was undertaken. This is combined with System sensitivity to calculate posterior confidence of freedom.

The results include:

- the sensitivity of the surveillance system, or in other words, the probability that the surveillance system would detect at least one infected animal if disease was present at the specified design prevalence.
- the level of confidence that the population is free of disease (at the design prevalence).
- For comparison, the sensitivity of the system and confidence of freedom if representative sampling were used are also shown, along with the sensitivity ratio. This indicates how much more sensitivity the risk-based approach acheives, relative to a representative approach.
- the effective probability of infection (EPI) for both high and low risk groups.

http://epitools.ausvet.com.au/content.php?page=RiskBasedSeSimple&RelRisk=2&PPr=0.1&PStar=0.05&Se=0.95&nH=25&nL=5&prior=0.5

Epi Tools - Simple risk-based...

Simple risk-based surveillance - calculation of surveillance sensitivity

Analysed : Wed Jun 20, 2018 @ 02:22

Inputs

Relative risk	2
Population proportion in high risk group	0.1
Design prevalence	0.05
Test sensitivity	0.95
Number of high-risk units sampled	25
Number of low-risk units sampled	5
Prior confidence of freedom	0.5

Results

	Surveillance sensitivity	Confidence of freedom
Risk-based	**91.6%**	**92.3%**
Representative	**76.8%**	**81.2%**
Sensitivity ratio	**1.19**	
EPI in high-risk group	**9.1%**	

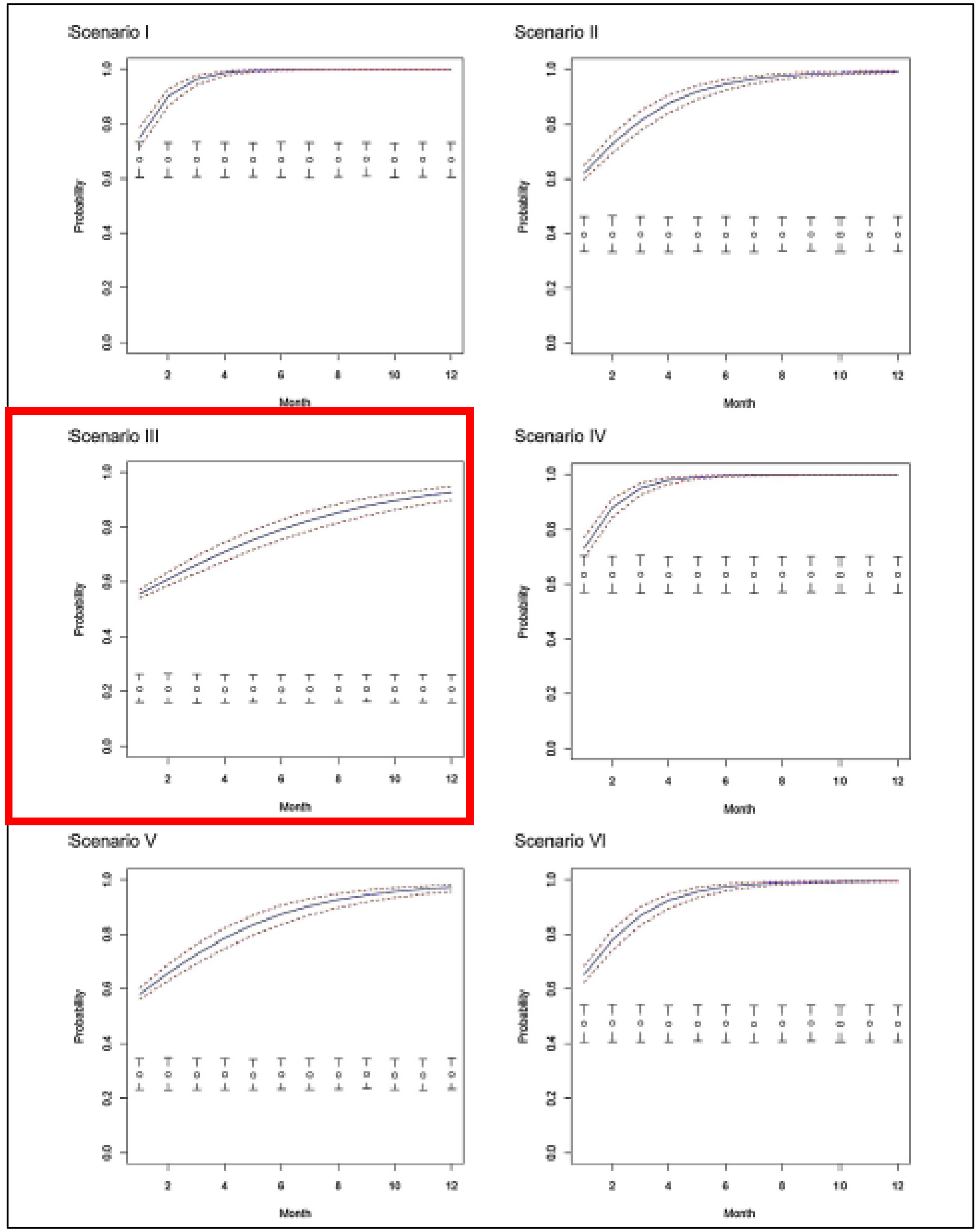
Inputs

Relative risk	2
Population proportion in high risk group	0.1
Design prevalence	0.1
Test sensitivity	0.95
Number of high-risk units sampled	25
Number of low-risk units sampled	5
Prior confidence of freedom	0.5

Results

	Surveillance sensitivity	Confidence of freedom
Risk-based	**99.4%**	**99.4%**
Representative	**95.0%**	**95.2%**
Sensitivity ratio	**1.05**	

Can also be calculated for other levels of clustering e.g. 2-stage sampling



Yearly inspection frequency:

I. 6 inspections for both Atlantic salmon (AS) & rainbow trout (RT)

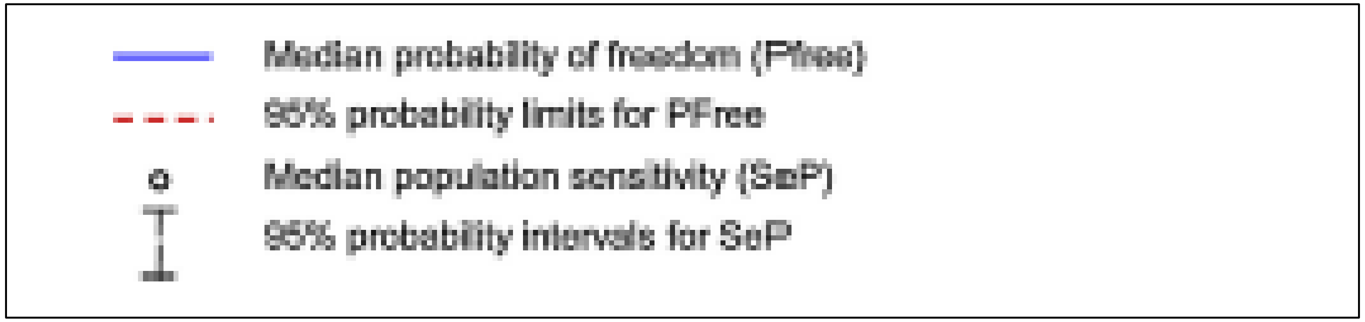
II. 3 inspections (AS & RT)

III. 6 inspections RT, 1 inspections AS

IV. 6 inspections (southern Norway), 3 inspections northern Norway

V. 6, 4 or 0 inspections depending on biosecurity level

VI. 6 or 3 inspections depending on production intensity



Conclusions

- There is an exciting variety of surveillance options
  - Purpose
  - Cost
- New approaches tend to be more complex
  - Start simple and build up depending on the requirements
- Use professional guidance when appropriate
- Good biosecurity and procedures
  - -> possibility for less intensive surveillance over time

References

- OIE *Aquatic animal health code* (current, online version)
- OIE Guide for Aquatic Animal Health Surveillance, 2009.
- FAO *Surveillance and zoning for aquatic animal diseases,* 2004
- Cameron, *et al* . (2002) *Survey toolbox for aquatic animal diseases – a practical manual and software package*. Australian Centre for International Agricultural Research (ACIAR).

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