Risk-based surveillance for human health hazards: the example of *Trichinella*

Alban, L.¹(1), Boes, J.¹, Kreiner, H.², Petersen, J.V.¹, Willeberg, P.²

¹ Danish Meat Association, Vinkel vej 11, DK-8620 Kjellerup, Denmark
² Danish Veterinary and Food Administration, Mørkhøj Bygade 19, DK-2860 Søborg, Denmark

*Lis Alban: lia@danishmeat.dk*

Abstract

Increasing demands for cost-effectiveness in surveillance for human health hazards can be met by introducing risk-based principles. This implies targeting subpopulations with higher risk of infection compared to the whole population. We demonstrate how historical data from surveillance can be used to assess risk of infection. The model is called "Discounting historical evidence" and depends mainly on two variables: Annual risk of introduction *P* intro and surveillance system sensitivity *S* Se (ability to detect infection if present). The model implies simulations that reiterate for a number of years, and for each year the output is updated with the confidence on absence of infection. *Trichinella spiralis* infection in pigs is used as an example. In Denmark, pigs at slaughter are tested (currently 23 million per year), and despite of >70 years of sampling no pigs have been found positive. Hence, we concluded that *P* intro is low. *S* Se can be estimated from the maximum number of infected carcasses expected under the specified design prevalence, and the sensitivity of the test applied. According to the assessment, the prevalence of *Trichinella* in Danish pigs is negligible (<1 case/ million). Based on this, a risk-based surveillance programme for *Trichinella* is designed that targets all out-door reared pigs as well as all sows and boars (currently 610,000 per year). Compared to confined pigs, outdoor-reared pigs have higher risk of getting *Trichinella* because of their exposure to wildlife, which might harbour *Trichinella*. Sows and boars are at increased risk, because they live longer than finishers. Again, *S* Se and *P* intro are estimated and the model is used to show how risk-based surveillance can be applied without jeopardizing human health. Finally, we incorporate wildlife surveys and test quality assurance in the programme. The model results are included in an application to the European Commission concerning Denmark’s status as a region with negligible risk of *Trichinella*.

Introduction

*Trichinella spiralis* is a zoonotic infection that previously constituted a common risk in many parts of the world. In Denmark, the surveillance programme for *Trichinella* is based on individual sampling of all pigs delivered to an export authorised abattoir. An increasing number of pigs have been surveyed since 1930, initially by use of the compression method, and since the 1970s by the digestion method (currently 22 m corresponding to 99% of the annual production). No pigs have ever been found positive during the more than 70 years that the programme has been in place. The question is whether a more cost-effective surveillance can be designed without jeopardising human health. Such surveillance should be risk-based, i.e. it should target the sub-population(s) with the highest risk of *Trichinella* since the aim is to detect infection if present. The question is how a risk-based approach would affect the ability to detect infection.

The present analysis aimed to:

1) Demonstrate that Denmark as a region has a negligible risk of *Trichinella* infection in domestic pigs
2) Design a risk-based surveillance system that is able to identify *Trichinella* infection in the national pig herd if it were present at a level above the chosen design prevalence
Method

A model called "Discounting historical evidence" was used for the analyses. The model was developed in connection with an Epilab Research Project in Copenhagen (Martin et al., in press). In the following, the model will be explained in more detail.

Two variables are of importance for the model:

1) the annual probability of introduction of *Trichinella* - *Plntro*
2) the sensitivity of the system (SSE) i.e. the surveillance system’s capacity to identify *Trichinella once the infection is present in the national pig herd above the level of the chosen design prevalence *P* *

We have looked at two different scenarios:

1) Current surveillance, where we simulated surveillance for the previous 16 years; from 1990 to 2006. In this period we have sampled all pigs in the entire population of slaughtered pigs
2) Risk-based surveillance where we only sample outdoor-reared pigs as well as sows and boars being slaughtered (610,000 pigs, 2005 estimate)

In each scenario, 10,000 simulations were run using the software programme @Risk (Palisade Inc.).

The choice of parameters describing *Plntro in the current surveillance was based on the fact that *Trichinella* has not been found in Denmark since 1930 (Maddox-Hyttel et al., 2003). The probability of infection next year (*Plntro*) can then be conservatively estimated as: 1 / (waiting time since last outbreak), corresponding to 1/76=1.3%. To account for variation in *Plntro* an interval of ±25 years was used, corresponding to a probability range of 1.0% to 2.0%. This approach captures changes in risk during the 76-year period of surveillance (the risk of introduction may have varied over the years), but since the current system has prevented introduction for 76 years, an estimated annual risk varying between 1.0% and 2.0% is considered a conservative estimate.

In a risk-based surveillance programme for *Trichinella* for slaughter pigs, outdoor-reared pigs as well as sows and boars will be sampled. Outdoor-reared pigs harbour a higher risk of introduction because of the possibility of contact with wildlife. Sows and boars are at increased risk because they have a longer possible exposure period compared to finishers. Wildlife surveys conducted in Denmark in 1974-75 (Maddox-Hyttel et al., 2003), 1996-97 and 1998-99 (Enemark et al., 2000) all revealed a very low (<0.1%) *Trichinella* prevalence in red foxes. This suggests a stable situation in the sylvatic *Trichinella* cycle in Denmark. Raccoon dogs *Nyctereutes procyonoides* typically show a higher prevalence and larval burden of *Trichinella* than foxes. The raccoon dog is currently not established as a species in Denmark but it is expected to spread into Denmark in the future. The exact magnitude of the increased risk of introduction from wildlife to outdoor-reared pigs compared to indoor-kept pigs is unknown. We therefore chose to model the risk as an interval, where the lower bound of *Plntro* was set at twice the risk that we found for indoor-kept pigs: *Plntrouside* = 2 x *Plntroinside* = 2 x 1/76 years = 1/38 years = 2.6%. As the upper bound of *Plntro* we used 3 x *Plntroinside* corresponding to 3.9%. Again, both bounds should be regarded as conservative estimates.

The surveillance system sensitivity (SSE) in the current surveillance can be estimated from the number of infected carcasses expected among the tested under the specified design prevalence, and the sensitivity of the test applied. We estimated that the prevalence of *Trichinella* in Denmark is negligible. According to EFSA (2005) this corresponds to less than one case per million individuals. Therefore, a design prevalence of 1/m was chosen. According to the literature, the test sensitivity might be as low as 40% in case only 1g of pig muscle is sampled, and only few encapsulated *Trichinella* larvae are present (3-5 larvae/g). If more larvae are present, or larger amounts of meat are digested, then the sensitivity is much higher than 40% (see Forbes & Gajadhar, 1999). To account for variability we assumed that the sensitivity of the individual test varied from 35% to 45%.
Based on the information about the expected number of infected animals and the sensitivity of the individual test, the system sensitivity in the present surveillance that includes all finishers was estimated to be 99.99% (Table 1). We assumed a design prevalence ($P^*$) of 1/m, implying that if Trichinella infection were present, the prevalence would be ≥1/m. This implies that at least 23 infected pigs are expected within a population of 23 m pigs. Because of the epidemiology of Trichinella, we expect that the main part of the 23 infected pigs will be present among the outdoor-reared pigs as well as the sows and boars. We assumed that 2/3 of the infected pigs would be found here corresponding to 15 out of the 23 infected pigs. Using these assumptions, the risk-based surveillance system chosen will have an SSe of 99.95% (Table 2).

Table 1. Estimated surveillance system sensitivity (SSe) for Trichinella in Danish pig production in the current system that involves testing of almost all pigs (currently 99%)

<table>
<thead>
<tr>
<th>SSe = Prob( identifying infection ) = 1-Prob( overlooking infection ) = 1-(1-Se)^23 = 0.9999</th>
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<tr>
<td>Where:</td>
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<td>Se = Test sensitivity = 0.40</td>
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<tr>
<td>D = Expected minimum number of diseased in population = $P^*$ x N = (1/m) x 23 m = 23 pigs</td>
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<tr>
<td>$P^*$ = Estimated design prevalence = 1/1,000,000 = 1/m</td>
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<tr>
<td>N = Size of total population, here the entire national pig herd = 23,000,000 pigs</td>
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<tr>
<td>n = Sample size = 23,000,000 pigs</td>
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Table 2. Estimated surveillance system sensitivity (SSe) for Trichinella in Danish pig production in a risk-based surveillance including outdoor-reared pigs as well as sows and finishers

<table>
<thead>
<tr>
<th>SSe = Prob( identifying infection ) = 1-Prob( overlooking infection ) = 1-(1-Se)^15 = 0.9995</th>
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</thead>
<tbody>
<tr>
<td>Where:</td>
</tr>
<tr>
<td>Se = Test sensitivity = 0.40</td>
</tr>
<tr>
<td>$D_1$ = Expected number of diseased in population = $P^*$ x N = (1/m) x 23 m = 23 pigs</td>
</tr>
<tr>
<td>$D_2$ = Expected number of diseased in sample= Prop x $D_1$ = 0.67 x 23 = 15 infected pigs</td>
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<tr>
<td>Prop = Proportion between infected pigs found in risk populations (outdoor-reared pigs/sows and boars) and in indoor-reared pigs = assumed to be 2/3 = 67%</td>
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<tr>
<td>$P^*$ = Estimated design prevalence in national herd = 1/1,000,000 = 1/m</td>
</tr>
<tr>
<td>N = Size of population, the entire national herd = 23 m pigs</td>
</tr>
<tr>
<td>n = Sample size = finishers raised outdoor as well as sows and boars in 2005 = 610,000</td>
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The simulation model updates the probability of infection in the national herd every year based on a combination of the probability of infection at the end of last year with the probability of introduction during the specific year. In the first year (1990) we assume that we have no knowledge of the infection; it might be present or not, i.e. we set the probability of infection to 50%, which is a very conservative estimate, since no cases have been found in the preceding 60 years. In each of the following 16 years we survey the pigs and do not find any positive pigs; by doing so we increase our confidence that we do not have the infection in the national pig herd, including our outdoor pig population.

Results

According to the simulation model there is a probability of 98.6% that the national pig herd in Denmark currently is free from Trichinella (Probability of free adjusted 95% Cl: 98.1%-99.0%). A high degree of confidence is obtained already after one year. This is mainly due to the large sample size. Hence, the risk is entirely driven by the annual risk of introduction $\text{Intro}$, which is estimated to 1.3%. In a simulation of the effect of risk-based surveillance, the probability of freedom from infection is again set to 50% in the first year, to simulate a situation without prior knowledge. Because of annual sampling with no positive findings the probability that the national pig herd is free from Trichinella in a risk-based sampling scheme increases to 96.7% after one year and remains stable thereafter (95% Cl: 96.1%-97.3%). This is a slightly lower probability than in the current system. Again, the risk is entirely driven by the annual risk of introduction $\text{Intro}$, which
is estimated at between 2.6 and 3.9% (mean 3.3%). As with the current system, the risk-based surveillance achieves a high level of sensitivity after just one year.

Discussion and conclusion

As pointed out by a previous risk assessment report (EFSA, 2005), the existence of true Trichinella-free areas/countries is very unlikely, because even though Trichinella may be absent in domestic pigs it may still be present in wildlife. What we can conclude from our simulations based on surveillance data from a 76-year period with increasing intensity is that the prevalence in domestic pigs in Denmark has been negligible and that Denmark is a low-risk area for Trichinella in pigs for slaughter. Therefore, risk-based sampling targeting sub-populations with higher risk is justified.

Sampling the entire population of 160,000 outdoor-reared pigs plus 450,000 sows and boars only gives a slightly lower confidence instead of sampling 23 m indoor-reared pigs. The negligible risk of infection among confined (i.e. indoor-reared) finishers is due to the strict biosecurity in place in Danish indoor pig herds. Hereby, outdoor-reared pigs will act as a sentinel for infection of Trichinella in the national herd. Similarly, testing of 450,000 sows and boars will act as an indicator of infection in individual herds in the event of infection in wildlife and biosecurity failing to prevent introduction of Trichinella. The sows and boars will be tested for Trichinella no matter if they are raised in confinement or outdoors, and no matter where they are slaughtered (export slaughterhouse or local butcher).

The model by Martin et al. (in press) assumed an “all other things equal” situation. For Trichinella, it may be argued that the advent of the raccoon dog means an increased risk of Trichinella transmission. If an infected raccoon dog harbours more Trichinella larvae than foxes (Oivanen et al., 2002), and if this results in a higher degree of exposure of outdoor pigs, then there is a higher likelihood that infection will be identified through the surveillance system in place. Moreover, the decreasing number of pig farms in Denmark will inevitably lead to larger indoor farms with better biosecurity.

The model results are included in an application to the European Commission concerning Denmark’s status as a region with negligible risk of Trichinella. A decision is expected in 2007. The proposed risk-based surveillance programme for Trichinella in Denmark will also include annual wildlife surveys, pig traceability, contingency plans and test quality assurance.

References