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Impact of a genetic variant of *Chlamydia trachomatis* on national detection rates in Sweden

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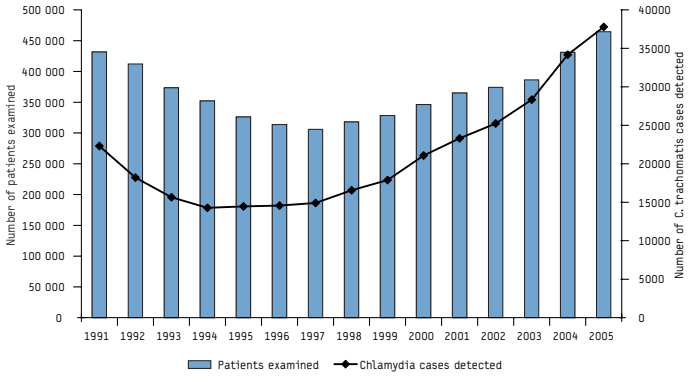
In the Swedish county of Halland, it was recently reported that a proportion of sexually transmitted *Chlamydia trachomatis* infections could not be detected using standard laboratory tests manufactured by Abbott and Roche [1]. Chlamydia bacteria with a variation in a genomic region targeted by PCR primers have been identified. A subsequent investigation to see whether the presence of genetic varients could be inferred from the basic epidemiological data reported from all 21 counties in Sweden has recently been completed.

In Sweden, four commercially available nucleic acid amplification assays are used for chlamydia routine diagnostics, although in most counties, only one assay is used. Three of the detection systems (two from Roche and one from Abbott) use the same PCR primer target region. The chlamydia genetic variant recently identified has a deletion in this region, therefore these tests cannot detect it [1]. The diagnostic test by BectonDickinson uses a different primer target region and can therefore detect this variant.

Chlamydia trachomatis infection is one of the 60 notifiable diseases under surveillance at a national level in Sweden. Chlamydia infections are reported both as individual clinical cases and as the number of people with detected chlamydia infections. The annual number of people in Sweden testing positive for chlamydia has consistently increased since 1994 (Figure 1).

Figure 1

Number of people with detected chlamydia infections, and number of people tested for chlamydia, 1991 - 2005*



* Even though the overall number of patients tested for chlamydia in 2006 is not yet available, on the basis of preliminary data, it is assumed to be the same as in 2005.

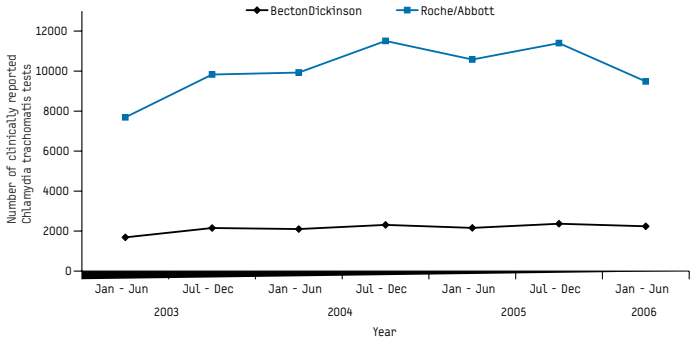
Detection of chlamydia infections by different methods

Data showing clinically reported cases reported between January 2003 and June 2006 according to diagnostic test used is presented in Figure 2. The data was provided by 20 laboratories covering the whole of Sweden, except three counties where laboratories either changed the detection method during the observed period or used both Roche and BectonDickinson systems. The data accounts for approximately 80% of all reported chlamydia cases in Sweden during the period from January 2003 to June 2006. In 2003 and 2004, the number of reported cases increased or stayed at a similar level regardless of the test used.

Due to seasonal variations in chlamydia infections, the incidence is higher in the second half of the year. However, the counties where laboratories used BectonDickinson tests reported a similar number of chlamydia cases in the first and second half of 2005, while the counties using Roche or Abbott tests reported fewer cases in the second half of the year.

Figure 2

Number of clinically reported chlamydia cases in Sweden from January 2003 to June 2006, by diagnostic method



This trend is even more visible when the first half of 2006 is compared with the same period in 2005. A 10% decline in number of chlamydia cases diagnosed with Roche or Abbott tests can be seen, compared with a 1% increase in cases detected with the BectonDickinson test. This could be caused by a nationwide distribution of a genetic variant of *Chlamydia trachomatis* being undiagnosed.

Discussion

At present, it is still unclear when the variant appeared (it still also not determined whether there are several clones), and how far it has spread in Sweden. There are considerable variations in case numbers from month to month between counties which use the same test and there is a lack of information about prevention and control measures (such as chlamydia prevention programmes) for each individual county.

We can assume that this genetic variant, because it is not being detected and treated, is spreading more easily than other strains. In counties that have used Roche/Abbott technology for several years, genetic variants may be more prevalent than in counties using alternative test systems. Due to the presence of chlamydia cases caused by a genetic variant, one laboratory (Örebro University Hospital) recently changed over from the Roche test system to diagnostics by cell culture.

Although data are still based on low numbers, the proportion of cases caused by the chlamydia genetic variant (negative by Roche PCR and a fraction confirmed by sequence analysis) accounted for 39% of all chlamydia cases during one month from unselected patients examined at primary health care/STI-/youth clinics. If this was a representative figure, the failure to detect this genetic variant would also have an effect on the complication rates of genital chlamydia infections. However, since complication risks are difficult to estimate and the rates of complication or infections are low in Sweden, it would be even more difficult to measure the impact of this chlamydia variant on public health [2].

Regardless of the exact proportion of chlamydia cases caused by the variant, it is evident that the failing diagnostic methods must urgently be modified to enable detection of all prevalent *C. trachomatis* strains. It appears that the present findings are an example of bacterial evolution driven by diagnostic methods. This could have been prevented by using double target genes of the infectious agent in the same test reaction, as has been applied for other pathogens [3].

Assuming that the recently discovered chlamydia variant is evenly spread throughout Sweden, using the data from Halland county as a basis, it can be estimated how much this would affect the nationally reported numbers. From January to September 2006, the number of clinically reported chlamydia cases in Sweden decreased by 6%, compared with the same period in 2005. If the case numbers from laboratories using Roche/Abbott test are compensated with a 13% 'loss in detectability' (13% was the proportion of missed cases in Halland county) a 4% national increase in chlamydia cases would have been expected compared with the same period in 2005. Assuming that the prevalence is increasing, as has been the trend since 1997, this 6% decrease could more easily be explained by a drop in detection rather than an actual decrease. Further data are still needed to determine the size of the problem of this chlamydia variant and failing detection systems. The results obtained so far highlight the importance of active monitoring of test accuracy and epidemiological surveillance.

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