Vaccine 29 (2011) 1283–1288

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Reliable surveillance of tick-borne encephalitis in European countries is necessary to improve the quality of vaccine recommendations

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ARTICLE INFO

Article history:
Received 26 May 2010
Received in revised form
18 November 2010
Accepted 23 November 2010
Available online 9 December 2010

Keywords:
Tick-borne encephalitis
Vaccination
Vaccine recommendations
Endemic area definition
Surveillance

ABSTRACT

In July–November 2009, 26 European Union (EU) Member States (MSs), Norway and Iceland, participated in a survey seeking information on national tick-borne encephalitis (TBE) vaccination recommendations. Information on TBE surveillance, methods used to ascertain endemic areas, vaccination recommendations, vaccine coverage and methods of monitoring of vaccine coverage were obtained. Sixteen countries (57%) reported presence of TBE endemic areas on their territory. Vaccination against TBE was recommended for the general population in 8 (28%) countries, for occupational risk groups – in 13 (46%) countries, and for tourists going abroad – in 22 (78%) countries. Although vaccination recommendations for country residents, and for tourists always referred to endemic areas, there was no uniform, standardized method used to define endemic areas. For this reason, clear recommendations for tourists need to be developed, and standardized surveillance directed to efficient assessment of TBE risk need to be implemented in European countries.

1. Introduction

Tick-borne encephalitis (TBE) is an acute disease of the central nervous system caused by viruses from the Flaviviridae family. Infection most commonly occurs following exposure to ticks infected with one of the 3 viruses belonging to the TBE complex [1]. Food borne transmission of TBE has also been increasingly reported following consumption of unpasteurised milk or dairy products [2,3]. The infection usually progresses biphasically. The first (viremic) phase often is asymptomatic or causes influenza like symptoms. Only about one third of cases progresses to the second phase which may present as meningitis, encephalitis, meningoencephalitis, meningoencephalomyelitis or cause other clinical syndromes. Post encephalitic sequelae (e.g. sustained paresis, ataxia, headache, hearing impairment) are reported in 35–58% of symptomatic patients [1]. Diagnosis of TBE is based on detection of specific IgM and IgG antibodies in serum or cerebro-spinal fluid using the enzyme-linked immunosorbent assays (ELISA), however cross-reactivity with other flaviviruses has been observed [4]. Neutralization testing allows confirmation of specific anti-TBE antibodies presence. There is no specific treatment for TBE. Although personal protective measures (such as covering limbs, wearing insect repellants and removing ticks), as well as avoidance of unpasteurised milk coming from endemic areas is usually encouraged, the only efficient measure of disease prevention is active immunization. In Europe two highly effective and safe vaccines are used

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0264-410X/$ – see front matter © 2010 Elsevier Ltd. All rights reserved.
doi:10.1016/j.vaccine.2010.11.077

for prevention of TBE infections and their chronic sequelae [5]. The two vaccines available are whole-virus inactivated products: FSME-IMMUN (Baxter AG, Vienna, Austria) and ENCEPUR (Novartis AG, Basel, Switzerland). Typically three doses are needed for primary immunization at 0, 1, 6–12 months, and booster doses every 3–5 years [5].

Despite availability of safe and effective vaccines, TBE is an increasing public health problem in Central and Northern Europe [6,7]. During the previous decade, on average 3000 clinical cases have been reported annually from European countries [6–9].

The optimal vaccination strategy is difficult to establish as TBE is a zoonotic disease, with highly focal natural distribution. Mass immunization would not affect the local circulation of the virus in enzootic cycles [10,11]. Theoretically, the best approach would be a combination of health promotion, vaccination of high risk groups, and, potentially, vector control measures. To define the best strategy for TBE control, however, good quality data are needed on TBE virus (TBEV) occurrence, as well as information on population-level and individual risk factors.

The aim of the present study was to summarize vaccine recommendations in European Union (EU) and European Economic Area (EEA) countries, in context of surveillance of human cases, and monitoring TBE endemic areas.

Box 1: Case classification used in three countries, results of VENICE survey, 2009.

Belgium	
Possible case:	Clinical criteria AND epidemiological link (travel to endemic area)
Probable case:	Clinical criteria AND epidemiological link (travel to endemic area) AND laboratory criterion (IgM in serum)
Confirmed case:	Clinical criteria AND laboratory criteria (seroconversion, fourfold antibody rise, PCR)
Germany	
Possible case:	NA
Probable case:	NA
Confirmed case:	Clinical criteria (biphasic course or CNS infection symptoms) AND laboratory criteria (IgM and IgG detection in serum, in CSF, or marked increase in antibody titre)
Poland	
Possible case:	Clinical criteria AND visit to endemic area during April-November
Probable case:	Clinical criteria AND epidemiological link (consumption of raw diary products) OR laboratory criterion (IgM in serum)
Confirmed case:	Clinical criteria AND laboratory criteria (IgM and IgG detection in serum, in CSF, and confirmation by neutralization test)

2. Materials and methods

A cross-sectional survey was undertaken as a collaborative study between the European Centre for Disease Control and Prevention (ECDC), the Vaccine European New Integrated Collaboration Effort (VENICE) project and EU/EEA Member States. The respondents of the survey were identified using a network of VENICE contact points among experts working with national vaccination programmes and TBE surveillance. Currently the VENICE collaboration involves representatives of 27 EU and two EEA (Norway and Iceland) countries.

A standardized questionnaire was developed in June–July 2009 using mostly close-ended questions. The questionnaire covered the following topics: surveillance of TBE, ascertainment of endemic areas, vaccination recommendations, vaccination coverage, payment and administration costs for the vaccine. The web-based platform was developed by CINECA (Consortium of University, Bologna, Italy), and the survey was made available on the platform for all participating countries. Respondents of the survey entered data directly on-line.

The questionnaire was pilot tested and its corrected version was published online in July 2009. Reminders were sent during the following three months in order to improve compliance. The collection of data was completed in November 2009. We have also asked national contact points to validate the preliminary report, and inconsistencies were further verified.

Collected data were analyzed using EpiInfo software and descriptive statistics were produced. Selected surveillance indicators and vaccination recommendations were compared. The present paper describes only selected indicators. The detailed survey report was published on the VENICE website for Members area, which will be made public by the end of 2010 (http://venice.cineca.org).

3. Results

We obtained filled questionnaires from 28 out of 29 countries (response rate 96%). We did not receive output from Luxembourg. The report was further validated by 71% (20/28) national contact persons. Among the 28 participating countries, eighteen (64%) reported evidence of TBE risk within their territory. Table 1 summarizes availability of surveillance data on TBE, and classification of TBE risk based on surveillance figures.

3.1. TBE surveillance

Surveillance for TBE was implemented in 17 (61%) countries. However, only in three countries (Belgium, Germany and Poland), a standardized case definition was used to classify cases reported to surveillance (Box 1). In four countries (Austria, Czech Republic, Finland, Greece) there was no standardized surveillance definition which was published and disseminated, but the surveillance system accepted only laboratory confirmed cases. All countries with TBE surveillance used ELISA tests to confirm cases, the majority of countries used also the polymerase-chain reaction (PCR) and immunofluorescence tests (Table 1).

Endemic areas existed in 16 countries (57%), including 14 countries where surveillance was set up, and two countries (Denmark and France), where no TBE surveillance existed. Only one country had an official definition of "endemic area". In Germany, an endemic area was defined by average recorded 5-year incidence of locally acquired cases in a district or region consisting of the district and adjoining districts significantly exceeding 1 case per 100,000 inhabitants. Based on this definition, experts from Robert Koch Institut prepared and disseminated maps of Germany presenting endemic areas, which were updated annually [12].

Amongst 16 countries with identified endemic areas, 10 (63%) used the number of TBE cases in administrative regions to ascertain their endemic areas, and 8 (50%) used reported incidence. Although many countries indicated diverse methods of confirmation of endemic areas presence (detection of virus in ticks, screening of sentinel animals), there was no indication that these methods were applied routinely, and repeatedly, in order to monitor eventual fluctuations in endemic areas extent. Fifteen countries (94%) disseminated information on TBE endemic areas to the public. The most common modality for dissemination was risk maps in printed materials or published on websites. Information on endemic areas was disseminated most commonly by the National Institutes of Public Health (81%), local public health authorities (75%), and vaccination centres (63%).

Table 1
Summary of surveillance systems for tick-borne encephalitis and surveillance data available in EU/EEA countries, results of VENICE survey, 2009.

Country	Surveillance of TBE	Type of reporting	Surveillance case definition	Diagnostic assays available at national laboratories[a]	Known endemic areas	Number of cases in 2007	Incidence per 100,000 (2007)
Austria	Yes	Mandatory	No	ELISA, VNT, PCR, HIA, SEQ	Yes	46	0.58
Belgium	Yes	Voluntary	Yes (2008)	ELISA, PCR	No	–	–
Bulgaria	No	–	–	–	No	–	–
Cyprus	No	–	–	–	No	–	–
Czech Republic	Yes	Mandatory	No	ELISA, CFT, VNT, IFA	Yes	546	5.00
Denmark	No	–	–	–	Yes	–	–
Estonia	Yes	Mandatory	No	ELISA, IFA, WB	Yes	140	10.40
Finland	Yes	Mandatory	No	ELISA, PCR, HIA	Yes	20	0.38
France	No	–	–	–	Yes	4	0.01
Germany	Yes	Mandatory	Yes (2001)	ELISA, VNT, PCR, IFA, VI	Yes	238	0.29
Greece	Yes	Mandatory	No	ELISA, PCR, IFA, VI	No	1	0.01
Hungary	Yes	Mandatory	No	ELISA, VNT, PCR, HIA, IFA, VI, SEQ	Yes	69	0.70
Iceland	No	–	–	–	No	–	–
Ireland	No	–	–	–	No	–	–
Italy	Yes[b]	Voluntary	No	ELISA, HIA, VNT	Yes	16	0.03
Latvia	Yes	Mandatory	No	ELISA	Yes	171	7.50
Lithuania	Yes	Mandatory	No	ELISA, PCR	Yes	234	6.89
Malta	No	–	–	–	No	–	–
Netherlands	No	–	–	–	No	–	–
Norway	Yes	Mandatory	No	ELISA, PCR, IFA	No	14	0.30
Poland	Yes	Mandatory	Yes (2005)	ELISA	Yes	233	0.61
Portugal	No	–	–	–	No	–	–
Romania	Yes[b]	Mandatory	No	ELISA, WB	Yes	67	1.44
Slovakia	Yes	Mandatory	No	ELISA	Yes	57	1.06
Slovenia	Yes	Mandatory	No	ELISA, PCR, IFA, VI	Yes	199	9.90
Spain	No	–	–	ELISA, PCR	No	–	–
Sweden	Yes	Mandatory	No	ELISA, VNT, PCR, IFA, WB	Yes	181	1.97
United Kingdom	No	–	–	–	No	–	–

[a] ELISA (enzyme-linked immunosorbent assay), CFT (complement fixation test), VNT (virus neutralization), PCR (polymerase chain reaction), HIA (haemagglutination inhibition assay), IFA (immunofluorescence assay), WB (Western blot),VI (virus isolation),SEQ (sequencing).
[b] Surveillance coordinated at sub-national level.

3.2. Vaccination recommendations and cost

At least one vaccine was registered in 22 (79%) countries. The different type of recommendations implemented in EU/EEA countries are summarized in Table 2. Vaccination against TBE was recommended for general population in 8 (28%) countries. The organization of recommendations was the following: partial subsi-

Table 2
Summary of vaccination recommendations in EU/EEA countries, results of VENICE survey, 2009.

Risk group	Recommendations at national level	Recommendations for inhabitants of endemic areas/regions
General population		
All age groups	Austria, Czech Rep., Slovenia	Estonia, Germany, Sweden
Specific age groups		Finland, Latvia
Occupational risk		
Forestry, woodcutting workers, forest rangers	Czech Rep., Estonia, Hungary, Latvia, Poland, Slovakia, Slovenia	Denmark, Germany, Finland
Agriculture workers	Estonia, Hungary, Poland, Slovakia, Slovenia	Germany
Military, Police, border guards	Czech Rep., Estonia, Latvia, Poland, Slovakia, Slovenia	Denmark
Every person working mainly outdoor	Czech Rep., Estonia, Slovakia, Slovenia	Denmark, Germany, Italy
Laboratory workers, who may be exposed to TBE	Czech Rep., Estonia, Germany, Latvia, Slovakia, Slovenia, United Kingdom	
Other	Estonia, Lithuania, Slovakia	
Other risk		
Outdoor sport	Slovenia	Denmark, Finland, Hungary, Italy, Slovakia, Norway
Holidays and leisure time (hike, camp, hunt)	Poland, Slovenia	Denmark, Finland, Hungary, Italy, Slovakia, Norway
Mushroom, berries collectors	Slovenia	Finland, Slovakia
Other		Germany, Latvia
Tourists		
Individuals travelling into an endemic area inside country	Austria, Czech Rep., Estonia, Finland, Germany, Hungary, Poland, Sweden, Slovakia, Slovenia	
Individuals travelling abroad	Austria, Belgium, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Norway, Poland, Romania, Slovakia, Slovenia, Spain, United Kingdom, Sweden	

dize (Austria, Czech Republic), free for risk groups (Slovenia), free for inhabitants of endemic areas (Germany), full cost paid by the recipients (Estonia and Sweden). In two countries recommendations concerned only specified age groups: younger than 18 years in Latvia, and older than 7 years in Finland (vaccines provided free of charge for inhabitants of endemic areas).

Vaccination recommendations for occupational high-risk groups were developed by thirteen (46%) countries. Apart from Finland, Denmark and Italy, those recommendations were not limited to specific regions. The vaccine was provided free of charge for occupational risk groups in nine (32%) countries. Recommendations for recreational risk groups existed in 11 (39%) countries, although the majority of countries developed recommendations directed only to inhabitants of endemic regions.

Some countries had recommendations for vaccination of other risk groups: agriculture and biology students in Estonia, and railway employees in Slovakia. In Latvia, individuals occupationally exposed to ticks were eligible for free-of-charge vaccination.

Vaccination was recommended to individuals travelling into an endemic area inside the country in ten countries (36%), and to tourists travelling abroad in twenty-two countries (78%). The most commonly used methods to disseminate travel recommendations were websites (17 countries), booklets (12), and technical documents published by public health agencies (4). Travel recommendations were available in vaccination centres (15), National Institutes of Public Health (14), local public health authorities (12), Ministries of Health (9), general practitioners offices (8), and travel agencies (6).

3.3. Vaccine uptake assessment

Seven countries (Austria, Estonia, Germany, Iceland, Latvia, Poland, and Slovenia) had established mechanisms for assessing TBE vaccine uptake. Six countries estimated vaccine uptake at national level, and one, Germany, at sub-national level. To obtain the numerator necessary for assessing TBE vaccine coverage, six countries (Austria, Estonia, Iceland, Latvia, Poland and Slovenia) used health record data, one country (Germany) estimated the vaccination coverage using immunization survey results and pharmaceutical sales data, without the possibility of individual data linkage. The numerator was calculated as the number of persons receiving at least one dose of the vaccine (Austria, Iceland, Latvia and Poland), or number of people who were vaccinated with 3 dose primary schedule during the previous 3–5 years or received a booster dose during the previous 3–5 years (Estonia and Germany). The estimated vaccine uptake in 2007 was 88% in Austria, 6% in Estonia, 9% in Latvia, and 0.8% in Poland.

4. Discussion

The present study was the first attempt to summarize TBE vaccination recommendations in European countries. Because TBE occurrence is characterised by high focality, vaccination strategy has to rely on precise information on areas, where the risk of disease is high (TBE endemic areas). According to the survey results, important disparities exist between European countries in the way the information on TBE cases and location of endemic areas is collected and disseminated to the appropriate stakeholders and general public. Due to lack of standardization, the sparse information available is not useful for development of clear, evidence-based vaccination recommendations.

Although most countries with known endemic areas implemented surveillance systems for TBE, their usefulness for development of vaccination recommendations is limited. First, reported cases in most countries are not classified using standardized case definition criteria. Only three countries implemented standardized case definitions, including clearly defined clinical, epidemiological and laboratory criteria, which are published by the public health agencies and used uniformly in the entire territory. If no case definitions are used, unconfirmed cases which are linked to food-borne TBE outbreaks will not be included in the surveillance system in at least four countries which accept only laboratory-confirmed cases. As surveillance case definitions are not used in most countries, detection of anti-IgM antibodies in serum is likely to be sufficient to confirm TBE cases. Considering its limited specificity, and broad cross-reactivity of TBEV ELISA tests with other flaviviruses, using this test can have different performance in countries where other flaviviruses (i.e. West Nile virus, Louping Ill virus) are circulating, compared to the countries where TBEV is the only flavivirus [4,14].

Second, routine reporting of human TBE cases may be influenced by the availability of resources for TBE diagnosis, and clear diagnostic protocols used by physicians in particular countries. As shown in previous investigations, in regions where TBE is a well known disease with a long-standing surveillance, its higher sensitivity is observed, mostly related to more common referring of patients for diagnostic testing [13,15]. The opposite situation is observed in regions reporting only sporadic cases, where physicians are less likely to perform diagnostic testing. It is possible that in many European regions, where surveillance is either not present or only developed recently, most TBE cases, including imported cases or cases resulting from food-borne transmission, will not be detected. This could also be true for regions free of TBE in countries where the presence of disease is documented only on part of the territory.

Third, information provided by routine TBE surveillance may be influenced by various interventions. For example, vaccination of a large population fraction will lead to decreased incidence, with TBE risk remaining the same, as depending on TBE virus circulation in enzootic cycles [10,11]. In this situation the risk depicted on an incidence map of locally acquired cases will be artificially decreased, providing unreliable information for visitors and foreign tourists.

Finally, human TBE surveillance is rarely supplemented by wildlife monitoring studies, which could be very useful in monitoring of endemic areas location and fluctuations. Although several such studies were performed in the recent years [16–18], there is no indication that they are applied systematically in all European regions to document objectively TBE risk.

Most recommendations directed to general population, and for persons exposed during recreational activities, relate to inhabitants of endemic areas. Only one country has to date developed a standard, measurable definition of endemic area, which is used to ascertain TBE risk annually, and is widely disseminated to health professionals, and general public [12]. Also, it does not take into account the fact that one locally acquired case could indicate an endemic area. Inversely, in a highly vaccinated community, no human TBE cases may be detected, therefore such definition should take into account indirect evidence from detection of TBEV virus from ticks or rodents. Some other countries that developed recommendations for endemic area inhabitants, are either not informing the community what they mean by “endemic area” or not disseminating this information properly. In the absence of clear definitions we are unable to state whether the term “endemic area” refers to boundaries of an administrative entity (community/municipality, district) or an arbitrarily selected region, where reported cases were mapped by place of exposure. Without a clear, uniform definition, an endemic area in one country will mean something different, than in another, often neighbouring country. This situation may constitute an obstacle for development of international travel recommendations, as they have to refer to specific travel destinations for which information on TBE risk should be easily available.

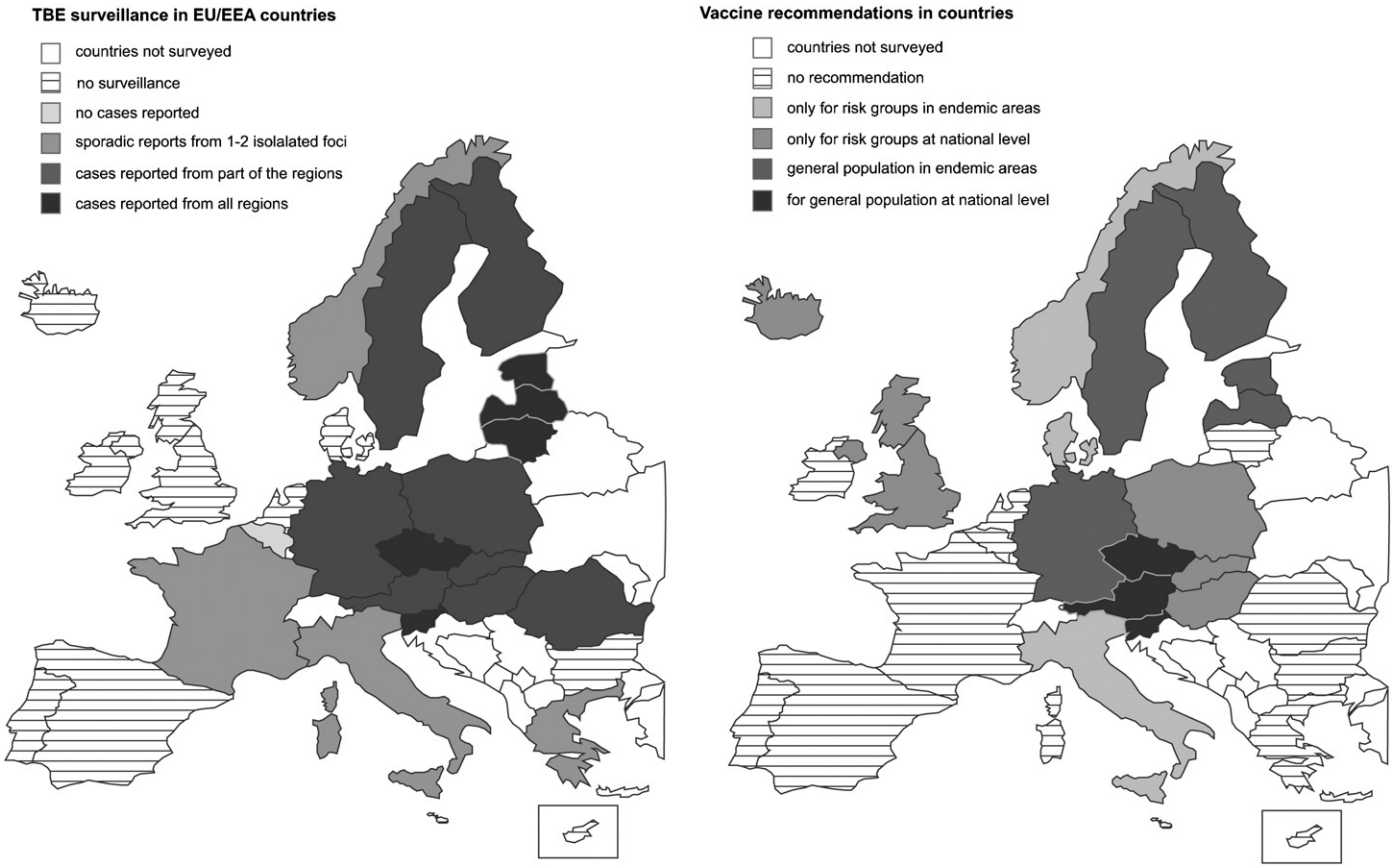

Fig. 1. Maps of Europe displaying the establishment of surveillance systems in EU/EEA countries (A), and vaccination recommendations for general population, results of VENICE survey, 2009.

One important finding of the present survey is that the vaccine is not registered in 6 countries, all of which are free of TBE endemic areas. If the vaccine is not available, it cannot be recommended to tourists visiting TBE endemic regions. In all the countries, where the vaccine was available, it was recommended for individuals planning to visit regions recording disease risk. As discussed previously however, the presence of endemic areas is not clearly defined, and is not easily accessed in most countries.

Also, important disparities were detected in the vaccine recommendations in EU/EFTA countries. Vaccination recommendations for the general population were not developed in several countries recording high TBE incidence at the national level. Also, development of recommendations for occupational risk groups was very diverse in European countries (Fig. 1). It is worth noticing that three countries recording TBE endemic areas (Lithuania, Romania and France), did not develop any kind of vaccination recommendations for high-risk groups. The high TBE incidence in Lithuania would particularly justify the development of targeted vaccination recommendations. On the other hand, two countries that do not record TBE endemic areas (Iceland and United Kingdom), developed recommendations for occupational and/or recreational risk groups.

It is difficult to assess the impact of existing vaccination recommendations on TBE epidemiology in Europe. The vaccine uptake is not regularly monitored in 92% of the countries not recording TBE cases, and in 60% countries possessing TBE endemic areas. Considering the need for regular booster doses for this specific vaccine, the figure included in the denominator as "fully vaccinated" should be defined as "3-dose primary schedule in recent 3 years or 3-dose schedule and booster dose within the previous 5 years". Currently, only two countries use systems which allow timely monitoring of vaccination coverage for fully vaccinated individuals. Since the vaccination coverage was high only in Austria, it is not likely that vaccination has had any impact on the TBE epidemiology in other European countries [19]. Assessing the impact of selective programmes directed to inhabitants of endemic regions or occupational risk groups is also problematic as neither region-specific nor risk group-specific vaccine uptake was routinely recorded.

5. Conclusions and recommendations

Universal or targeted vaccination against TBE can positively impact the overall burden of disease in endemic countries [20], but cannot decrease the TBEV circulation. Standardization of surveillance systems in EU/EEA countries is necessary to allow development of TBE vaccination recommendations addressing appropriate target groups in endemic areas. Such recommendations are strongly needed for international travellers. Application of surveillance case definitions, and encouraging laboratory confirmation of CNS infections, will allow appropriate assessment of disease burden, related to occupational exposure, exposures related to leisure activities, and food-borne exposures. Despite local occurrence of TBE only in part of EU countries, increasing travel, and free trade of food products in EU, requires prioritization of TBE surveillance at European level. Public health authorities should consider the inclusion of TBE in the list of diseases under European surveillance.

Development of vaccination recommendations, especially directed to travellers, necessitates adoption of compatible definitions of endemic areas across European countries. Based on clear definitions of endemic areas, risk maps should be widely disseminated, using national public health authorities, vaccination points,

and travel agencies. Also, a reliable mechanism of vaccination coverage assessment needs to be implemented in order to efficiently monitor the impact of vaccination recommendations.

Funding

The study was funded by the ECDC grant no. 2008/006: Improving Vaccination Programmes in the European Union and EEA/EFTA countries: Information Knowledge Performance (VENICE II).

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