# Estimating the Burden of Vaccine-Preventable Insect-Borne Diseases Without Vaccination Alternatives in Europe: What's going on in Spain and Germany?

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## OBJECTIVES

- Amidst increasing reports on insect-borne diseases in Europe due to on-going and expected climate change[1], we aimed to analyse the burden of prevalent preventable ones that despite a dynamic pipeline have no vaccination alternatives, using only publicly available data. We selected Lyme disease and Leishmaniasis.
- Lyme disease, is the most common tickborne disease in Europe; >200,000 cases per year are diagnosed and treated in western Europe[2], with important differences across countries. While the annual prevalence of Lyme disease in Spain is known to be 0.25/100,000[3], in Germany it has been estimated at 408 per 100,000 population[4].
- The estimated number of human cases of Leishamiansis in the European Region is 10,000-20,000 per 100,000 population[5].

## METHODOLOGY

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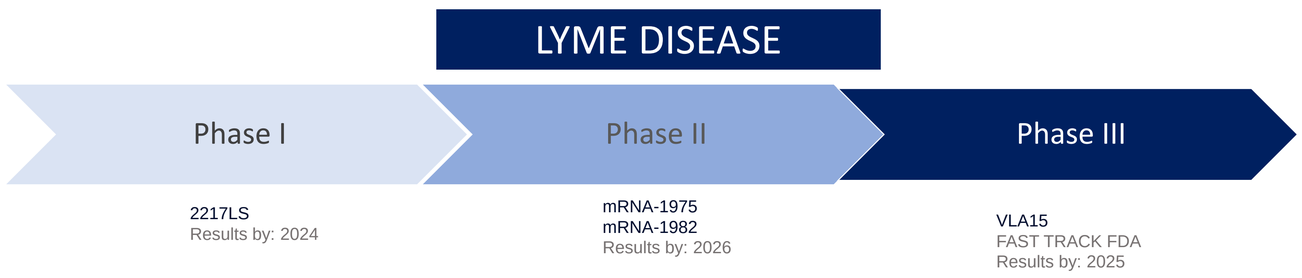
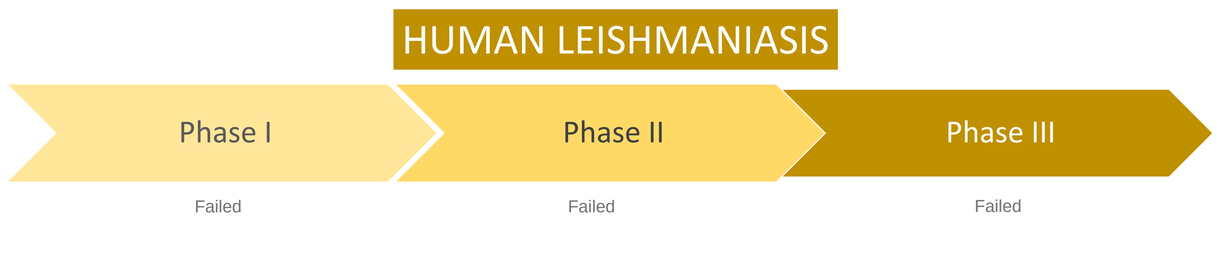
- Firstly, we reviewed ClinicalTrials.gov[6] to identify insect-borne diseases that are experiencing growing clinical research for prevention strategies but without approved vaccine alternatives.
- For the analysis we used aggregated retrospective real-world data from the Spanish National Hospital Discharge Database (RAE-CMBD)[7] and the Institute for the Hospital Remuneration System (InEK)[8] in Germany, that were publicly available.
- The following ICD-10 codes were used: A69.20; A69.21; A69.22; A69.23; A69.29 for Lyme disease and B55.0, B55.1, B55.2, B55.9 for Leishmaniasis.
- Due to availability of public data and for comparability purposes we extracted the following variables: annual number of hospitalised patients (transformed to annual rate) and mean length of stay (LoS) in hospital ward.
- The mean cost per patient was available in RAE-CMBD, but not in InEK, therefore we approximated it using the associated DRGs, their weights and the Bundesbasisfallwerte[9].
- For Spain, data from 2016 to 2021 was available; but for Germany we only had access to data from 2019 to 2022.

## RESULTS

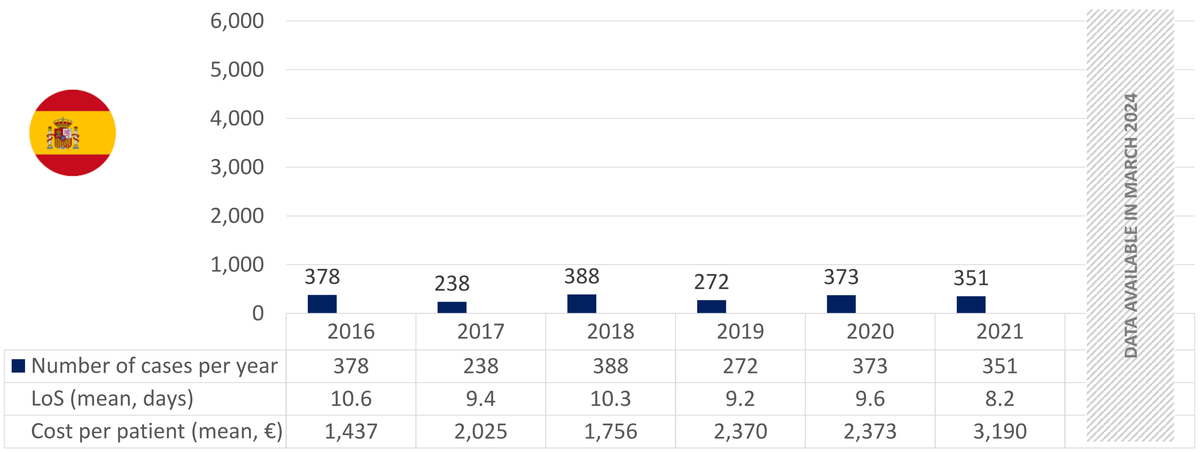
- Currently four vaccines to prevent Lyme disease are in clinical stage development (phase III results expected by 2025). Despite numerous attempts there is no-ongoing successful clinical development for Leishmaniasis.



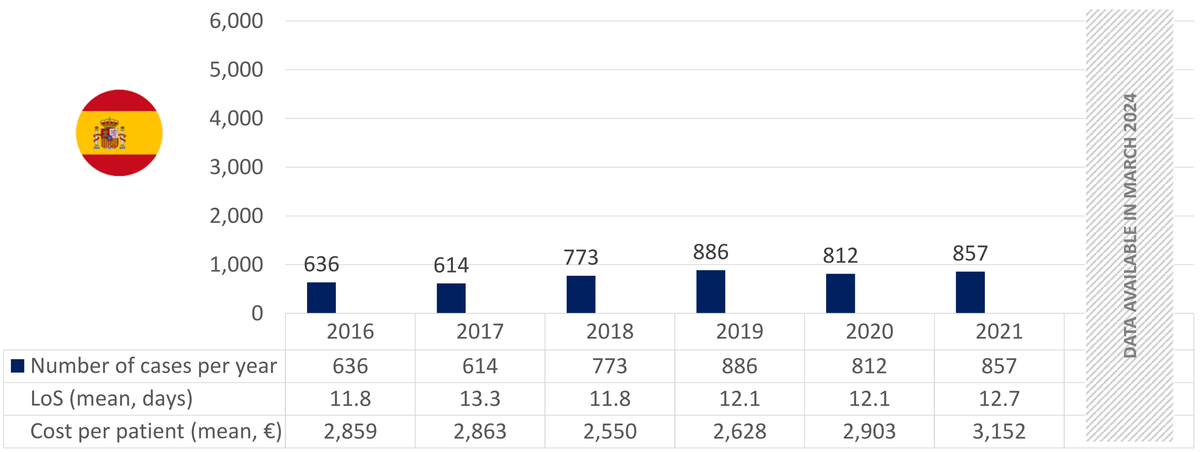




- A total number of 2,000 hospitalised cases of Lyme disease were reported between 2016 and 2021 in Spain. The mean LoS/patient was 9.6 days, and the mean cost was €2,178/patient; that led to a total in-hospital spending on Lyme disease of €4.4M.
- In Germany, the mean LoS/patient during 2019-2022 was 8.9 days and the mean cost/patient was €3,311/patient. However, overall, a lot more hospitalized cases were reported during a shorter period (21,558 cases from 2019 to 2022), leading to a total hospital spending of €71.5M.

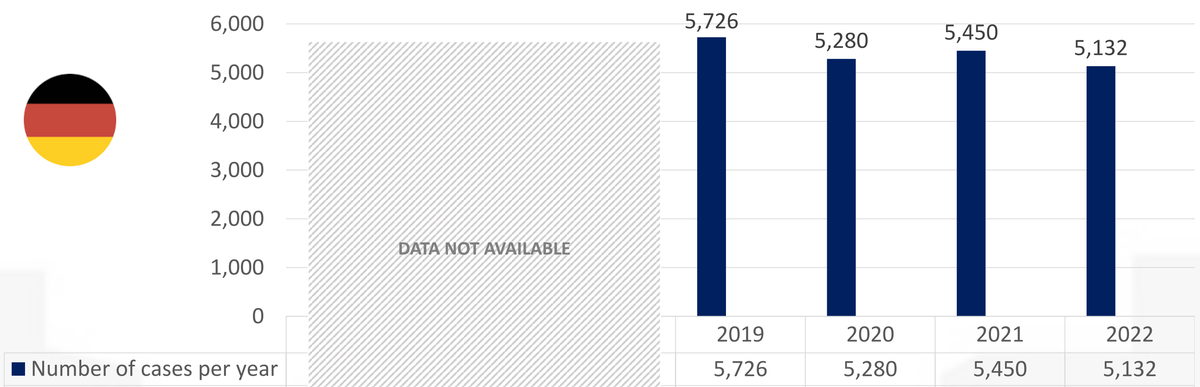
- A total of 4,578 hospitalised cases of Leishmaniasis were registered between 2016-2021 in Spain. The mean LoS/patient was 12.3 days and the mean cost €2,825/patient; that led to a total spending on Leishmaniasis hospitalisations of €12.9M.
- In Germany, the mean LoS/patient during 2019-2022 was 8.0 days and the mean cost/patient was €4,834patient. With a total of 169 hospitalized cases from 2019 to 2022 the total hospital spending was €1.3M.



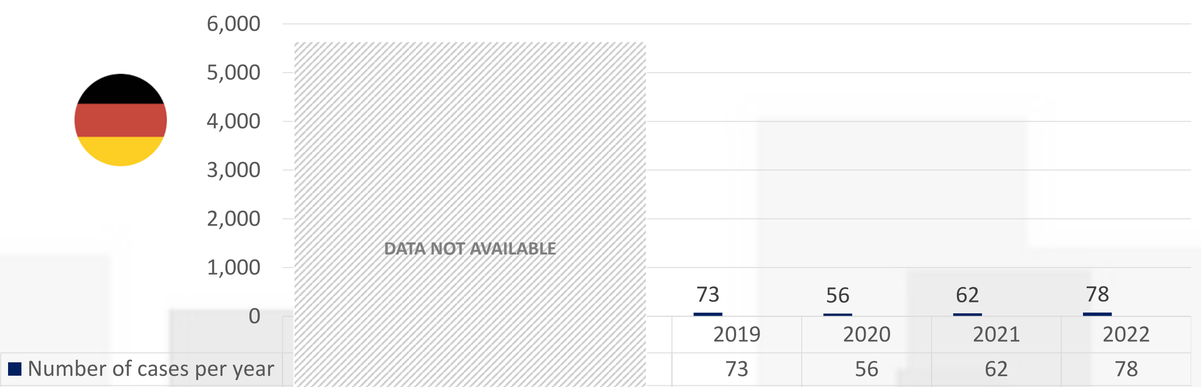

| | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|---|---|
| Number of cases per year | 378 | 238 | 388 | 272 | 373 | 351 |
| LoS (mean, days) | 10.6 | 9.4 | 10.3 | 9.2 | 9.6 | 8.2 |
| Cost per patient (mean, €) | 1,437 | 2,025 | 1,756 | 2,370 | 2,373 | 3,190 |




| | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|---|---|
| Number of cases per year | 636 | 614 | 773 | 886 | 812 | 857 |
| LoS (mean, days) | 11.8 | 13.3 | 11.8 | 12.1 | 12.1 | 12.7 |
| Cost per patient (mean, €) | 2,859 | 2,863 | 2,550 | 2,628 | 2,903 | 3,152 |




| | 2019 | 2020 | 2021 | 2022 |
|---|---|---|---|---|
| Number of cases per year | 5,726 | 5,280 | 5,450 | 5,132 |
| LoS (mean, days) | 8.8 | 8.9 | 8.9 | 8.9 |
| Cost per patient (mean, €) | 3,874 | 3,152 | 3,058 | 3,116 |




| | 2019 | 2020 | 2021 | 2022 |
|---|---|---|---|---|
| Number of cases per year | 73 | 56 | 62 | 78 |
| LoS (mean, days) | 7.2 | 7.5 | 7.1 | 9.8 |
| Cost per patient (mean, €) | 5,148 | 5,200 | 3,272 | 5,519 |

## CONCLUSIONS

- Our preliminary analysis showed that in recent years, insect-borne diseases such as Lyme disease and Leishmaniasis caused a substantial burden on hospital resources in at least two European countries presenting different epidemiology but also different healthcare provisioning models. Increased surveillance of insect-borne diseases and efforts to analyse real-world data have the potential to confirm the trends in this analysis and may inform effective resource allocation for prevention.
- One of the limitations of this preliminary analysis, is that given the aggregated nature of the data, we only performed a descriptive analysis. This is a limitation of major public healthcare databases in an effort to protect patient privacy. However, more complex study designs and analysis can be performed working together with health authorities and other interested stakeholders. For example, for research purposes, Spanish RAE-CMBD allows the request of anonymized patient level data to perform analyses based on real life outcomes adjusted by age, sex, severity (Charlson-index), hospital type or region.

1. Increasing risk of mosquito-borne diseases in EU/EEA following spread of Aedes species. Available at: https://www.ecdc.europa.eu/en/news-events/increasing-risk-mosquito-borne-diseases-eueea-following-spread-aedes-species; 2. Marques AR, Strle F, Wormser GP. Comparison of Lyme Disease in the United States and Europe. Emerg Infect Dis. 2021 Aug;27(8):2017-2024. 3. Surveillance, prevention and control of leishmaniases in the European Union and its neighbouring countries. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/leishmaniasis-surveillance-eu.pdf. 4. Vázquez-López ME, Pego-Reigosa R, Díez-Morrondo C, Castro-Gago M, Díaz P, Fernández G, Morrondo P. Epidemiología de la enfermedad de Lyme en un área sanitaria del noroeste de España [Epidemiology of Lyme disease in a healthcare area in north-west Spain]. Gac Sanit. 2015 May-Jun;29(3):213-6. Spanish. doi: 10.1016/j.gaceta.2015.01.008. 5. Olsen J, Angulo FJ, Pilz A, Halsby K, Kelly P, Brestrich G, Stark JH, Jodar L. Estimated number of symptomatic Lyme borreliosis cases in Germany in 2021 after adjusting for under-ascertainment. Public Health. 2023 Jun;219:1-9. doi: 10.1016/j.puhe.2023.03.002.6. www.clinicicaltrials.org. 7. Spanish National Hospital Discharge Database (RAE-CMBD). Available at: Spanish National Hospital Discharge Database (RAE-CMBD). 8. https://datenbrowser.inek.org/. 9. https://reimbursement.institute/glossar/bundesbasisfallwert/