Cost-Effectiveness Analysis of a Potential Vaccine to Prevent Colonization by *Helicobacter pylori* in the South-European Context

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Background and objectives

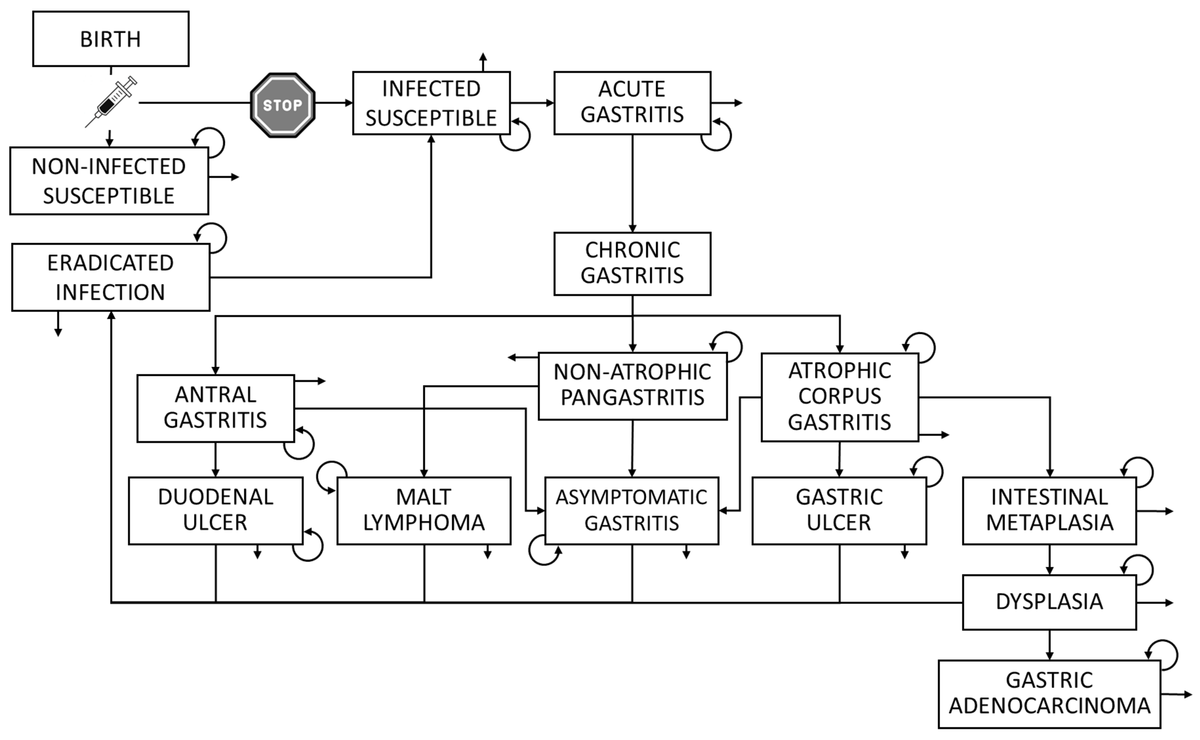
- Several *Helicobacter pylori* vaccines are currently under development to prevent infection. Nevertheless, all of them are in preclinical stages.
- There is evidence that a UreB/LTB fusion vaccine is effective in reducing *H. pylori* infection rate to 55.8% after 3 years. However, its development has been discontinued.
- A prototype of an *H. pylori* oral vaccine has received European funding and aims to achieve protection against mucosal colonization.
- Our objective is to quantify the cost-effectiveness of such a vaccine in our regional context and under several assumptions based on already available data.

Design and methods

Modelling and assumptions

- Both deterministic and probabilistic approach.
- Comparisons between two scenarios: 1) No vaccination and 2) Vaccination with a prophylactic intention in the first year of life.
- Some of the infected undergo eradication attempts than can be effective or not.
- Reinfection allowance if previous eradication.
- Simplification: 1) Duodenal ulcers only appear after antral gastritis and 2) Gastric ulcers and metaplasia only does so after atrophic gastritis.
- Health care sector perspective.
- Time horizon: 84 years (regional best life-expectancy).
- Complete vaccination: 1 + 3 booster doses.
- Willingness to pay per QALY: €24,506.

Compartmental model



Model implementation

- Annual transfer rates (r) between compartments were inferred from $r = (-1/t) * (\ln(1-P))$, where P is the probability of transition obtained from the primary sources and t is the number of years referred to by P.
- Discount rate for both costs and future effects: 3.5%.
- Governing equations for probability densities were mostly those of either a log-normal or a beta distribution. Only the vaccination price was forced to behave according to a uniform distribution between assumed min and max values.
- Annual cycles were simulated on a Microsoft Excel spreadsheet. The Monte-Carlo simulation was performed with the Statistical add-in for Excel XLSTAT Premium.

Model input variables

Variable	Base value	Reference
Non susceptible population	20%	Rupnow 2009
Incidence of *H. pylori* infection in <10 years	48.16/1,000/year	Hoi 2017
Incidence of *H. pylori* infection in >10 years	0.94/1,000/year	Hoi 2017
Effectiveness of the vaccine	80%	Rupnow 2000, Zeng 2015
Effective eradication rate for non-oncological conditions	70%	Choi 2020
Effective eradication rate for dysplastic gastritis	20%	Assumption
Infection recurrence	24/1,000/year	Gómez 2004
Transition parameter between compartments	Several values	Suerbaum 2002, Go 2002

Mortality and quality adjustments	Base value	Reference
Age-related mortality	According to age	Spanish Statistical Office 2018
Mortality due to duodenal ulcer	4.9% in 10 years	Rupnow 2009
Mortality due to gastric ulcer	9.5% in 10 years	
Mortality due to gastric cancer	72% in 5 years	Spanish Network of Cancer Registries
Mortality due to MALT lymphoma	11.3% in 5 years	
Quality adjustment due to gastritis and peptic disease	89%	Barkun 2010
Quality adjustment due to oncological conditions	50%	Rupnow 2009

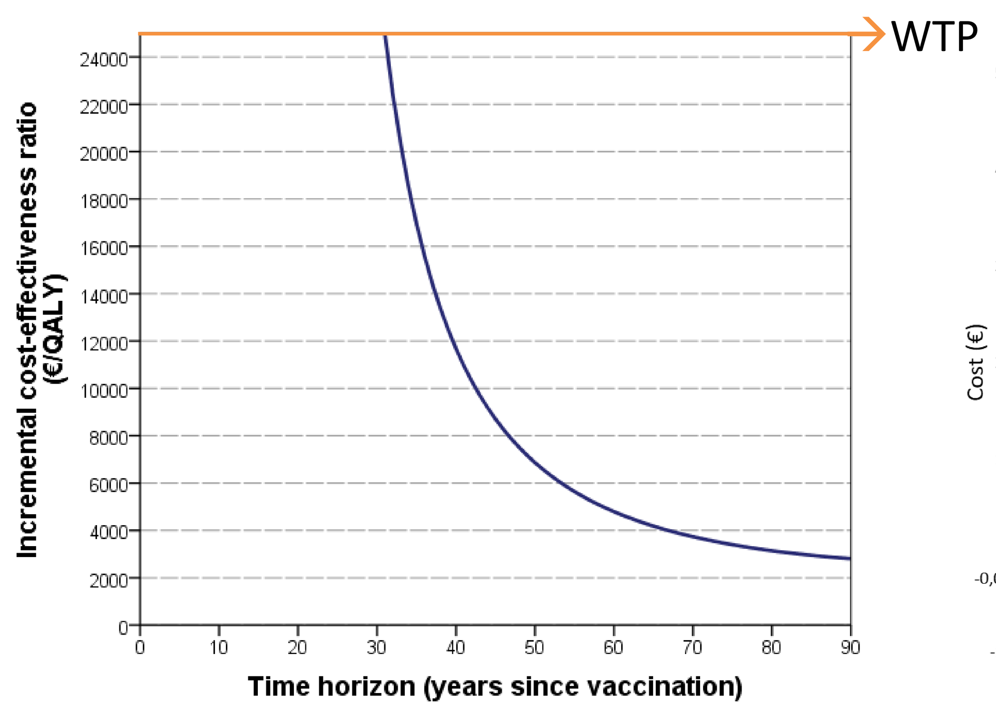
Vaccine and *H. pylori*-related conditions costs

Parameter	Cost per capita (in 2021 €)	Reference
Vaccine dose	206.6 (from 28.2 to 413.1)	Rupnow 2009
Vaccine administration	50.0	Catalan Government Gazette 2020
Vaccine side effects	0.0 (from 0.0 to 13.5)	Willems 1981
Peptic disease	4313.4	Hospital, primary care and pharmacy costs gathered from the Information System of the Catalan Health Institute
Oncological conditions	19.469.3	
Indications for eradication	68.5	

Results

Deterministic model

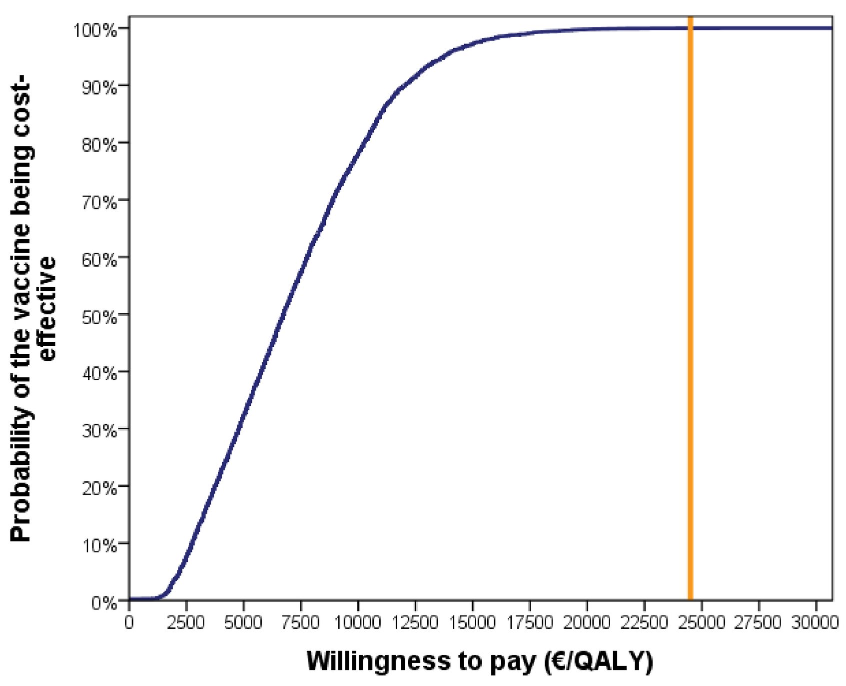
	Cost (per capita)	LY (per capita)	QALY (per capita)
Vaccination	200.20 €	26.17	25.13
No vaccination	993.24 €	26.37	25.42
Difference	**793.04 €**	0.20	**0.30**
	Incremental cost-effectiveness ratio		
€/LY	3,935.68		
€/QALY	**2,688.11** → below willingness to pay threshold		



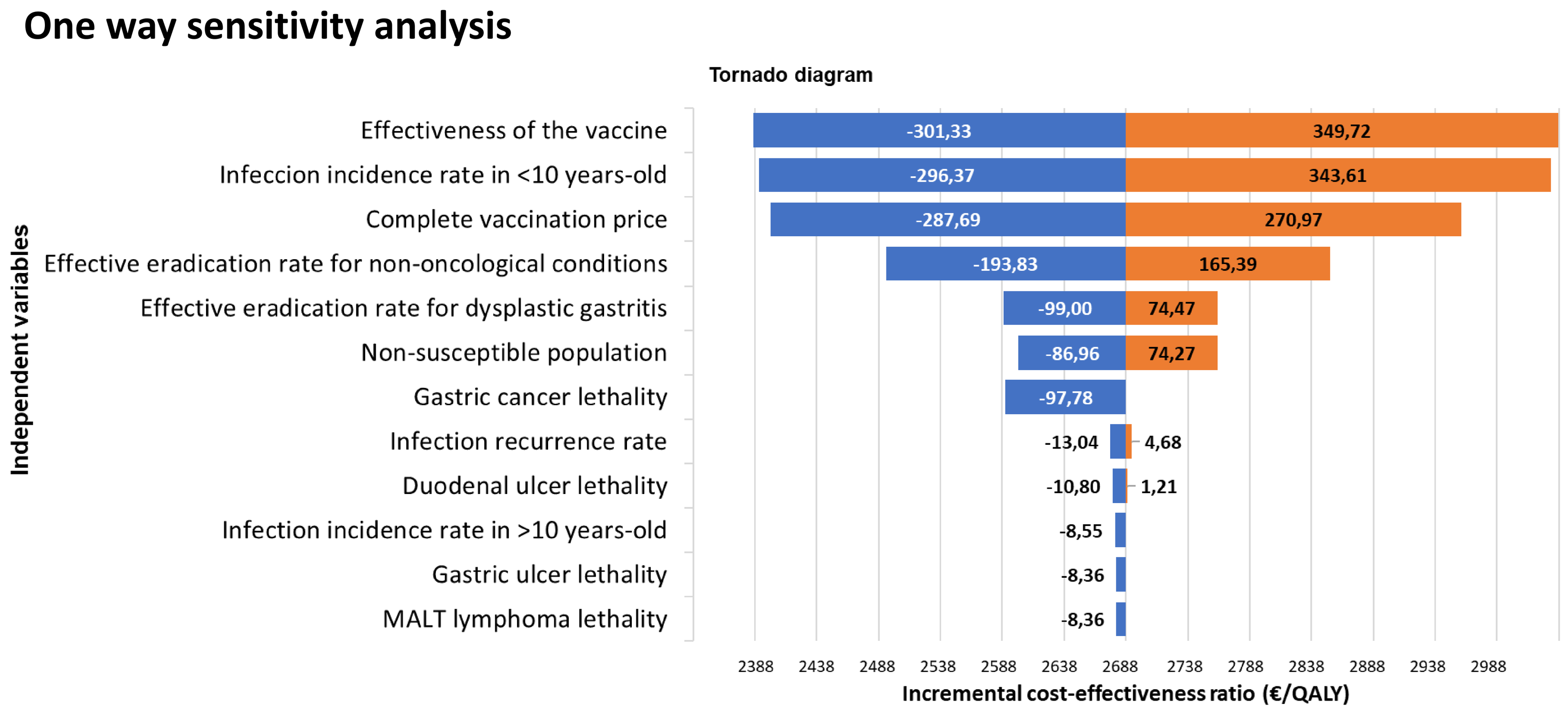
Probabilistic model

Only **0.04%** of the 5,000 simulations above the willingness to pay threshold (orange line)

Acceptability curve



One way sensitivity analysis



Vaccine dose price

Dominant	Cost-effective	Non-cost-effective

16.6 € — 3,631.4 €

Effective immunization coverage

2,042.0 €/QALY (+0,41 QALY)	Non-cost-effective

100% — 10.5% (+0,04 QALY)

Conclusion

When implemented in an environment with the epidemiological and economic characteristics of Southern Europe, a prophylactic vaccination against *H. pylori* would be cost-effective as early as 30 years from the beginning of the immunization program. This conclusion keeps being valid even when considering more disadvantageous vaccine prices and vaccine effectiveness rates.

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