Supplemental Material to:

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Cost-effectiveness of vaccination against herpes zoster

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Appendix A

In general, three types of analysis can be distinguished in health economic/pharmacoeconomic research[1]:

1) Cost-benefit analysis (CBA): only monetary units are involved in the economic evaluation. Costs and benefits are compared and outcomes are commonly presented as cost-benefit ratios. A specific type of CBA relates to cost-minimization analysis, with the focus on costs and savings in generally the health-care sector only.
2) Cost-effectiveness analysis (CEA): includes health consequences of the intervention, next to monetary outcomes. Results are presented as cost per case prevented, death avoided or life years gained; i.e. per clinical outcome.
3) Cost-utility analysis (CUA): is an extension of cost-effectiveness analysis, in which also the impact on both length and level of quality of life are incorporated. Results are presented as costs per quality-adjusted life year (QALY) gained. Notably, the QALY is an outcome which is able to incorporate gains from reduced morbidity as well as from reduced mortality.

In practice, CEA and CUA are not strictly distinguished, implying that studies expressing results in costs per QALY gained are often labeled as cost-effectiveness studies. For HZ and its main complication postherpectic neuralgia (PHN) fatal cases are rare, but there is a huge impact on health-related quality of life because of pain and discomfort. Therefore, a CUA is certainly the most suitable form of analysis to reflect the total impact of HZ vaccination on the disease burden in a certain country.

Costs

Which costs a study includes in the analysis highly depends on the viewpoint of the study or the perspective taken. Authors usually follow the national guidelines to decide from which perspective the study should be conducted. In general three perspectives are often used; i.e.(i) the health care payer's perspective, (ii) the third-party-payer's perspective and (iii) the societal perspective. The health care payer's perspective includes only direct medical costs, e.g. costs of GP-visits, medication and hospitalization. The third-party payer's perspective only considers reimbursed costs, hence, costs of over the counter drugs and other patients' own payments are not included. The societal perspective is the broadest viewpoint and includes - in addition to the medical costs - also costs for the society (indirect costs), for instance productivity losses due to work absence.[1] To deal with inflation, a recent base year has to be assumed in the analysis and all costs should be converted to this base year using consumer or health-care specific price indexes.[2]

Quality-adjusted life years

QALYs reflect life years weighted by the health related quality of life. For example, the QALYs which can be gained by preventing one case of PHN is the multiplication of the time spent in the PHN health state with the health-related quality attributed to the PHN health state. Health-related quality of life is determined by preference or utility to be in a certain health state - the more preferable an outcome, the more utility associated with it – and is measured on a scale between 0 (death) and 1 (perfect health). To estimate utilities, many instruments are available and it would be very arbitrary to rank these instruments from best to worse.[1] However, validated generic instruments like EQ-5D and SF36 are often used. The EQ-5D, for example, identifies a specific health state on five domains, i.e. mobility, self-care, usual activity, pain/discomfort, and anxiety/depression, and each domain has three levels, i.e. no problem, some problems, and major problems.[3]

Time-horizon & Discounting

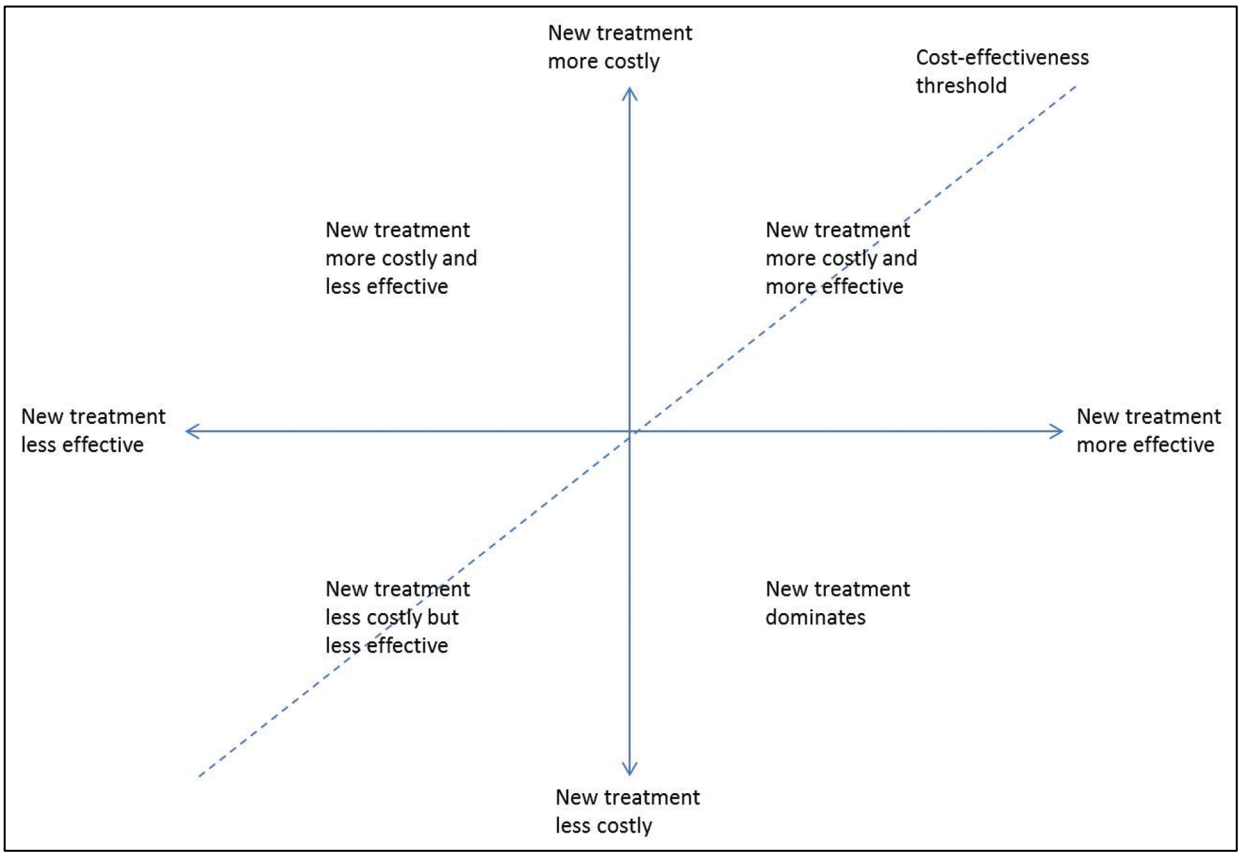
The time-horizon of an economic analysis has to be long enough to capture all the differential effects of the intervention as compared with the current situation.[2] In the case of HZ vaccination the lifetime horizon is obviously the optimal time horizon. However, when the time horizon exceeds 1 year, costs and health effects should be discounted. Discounting adjusts benefits and costs for the so-labeled 'time preference', since it is generally seen an advantage to receive a benefit earlier or to pay costs later. Most national guidelines of western countries recommend discount rates between 1.5 and 10%.[4] However, there is much debate on the question as to whether health benefits should be discounted and, if so, whether the discount rate for health benefits should be equal to that used for costs.[5] Most countries recommend to use equal discount rates for future costs and health gains , while other countries, including the Netherlands and Belgium, discount health gains at a lower rate than costs.[4] In general, the use of equal discounting rates for costs and health gains results in less favorable incremental cost-effectiveness ratios (ICER) as compared with differential discounting. Discount rates can have major influences on cost-effectiveness outcomes of vaccination strategies, mostly because of the long time span between costs and health effects.[6] Notably, studies should apply discount rates according to the national guidelines. When national guidelines are not available, discount rates of 3 or 5% are recommended. Extensive sensitivity analysis should be done on the discount rates.

Incremental cost-effectiveness ratio

Interventions should always be compared with the current situation; i.e., an incremental analysis should be done. Here, additional costs of the intervention are related to the additional costs/benefits or health effects of the outcomes.[1] The formula to calculate the incremental cost-effectiveness ratio is shown in the equation below. This formula implies that the incremental net costs (costs minus savings) are divided by the incremental effect outcomes (e.g., QALYs gained)

$$ICER = \frac{CostNew - CostExisting}{EffectNew - EffectExisting}$$

The cost-effectiveness plane is a useful tool to interpret cost-effectiveness results (Appendix Figure 1). In this diagram, the horizontal axis represents the difference in effect between the intervention and the alternative and the vertical axis represents the difference in cost. When the new treatment is more effective and less costly, the result falls in the south-eastern quadrant and dominates the existing treatment. However, when the new treatment is more effective but also more expensive, the cost-effectiveness threshold determines whether an intervention can be regarded as cost-effective (Appendix Figure 1; dashed line). Similar reasonings can be developed for the remaining two quadrants.



Appendix Figure 1

Cost-effectiveness threshold

The cost-effectiveness threshold or willingness-to-pay implies how much a government or a third party, such as a health-care insurance company, wants to pay to gain one unit on the effect measurement scale (e.g. QALYs). In some countries, no official willingness-to-pay threshold exists (e.g. the Netherlands, France), while others apply a certain range (Canada, US) or a strict value (UK). Referring to a statement of the World Health Organization (WHO), many countries consider that a value below the gross domestic product (GDP) per capita can be regarded as very cost-effective and below twice the GDP as still potentially cost-effective.[7] This implies that in western countries the willingness to pay ranges from approximately €20,000 to €50,000 per QALY gained.

Sensitivity analysis

To deal with uncertainty, studies generally perform sensitivity analyses investigating the impact of varying parameters on the study results. The simplest form of sensitivity analysis is a one-way analysis in which estimates for each parameter are varied once at the time. When more parameters are varied at the same time, the sensitivity analysis is labeled multiway. However, a limitation of the

multiway analysis is that the number of total combinations may become very large and results therefore difficult to interpret. An approach to present results of a multi-way analysis in a more structured way is to perform scenario analyses, in which a subset of potential multi-way analyses can be shown of which the analyst feels they could apply in a specific situation. Yet another form of sensitivity analysis is the probabilistic sensitivity analysis. Here, probability distributions are applied to the key parameters and samples drawn at random from these distributions to generate a distribution of the cost-effectiveness ratio. The proportion of the generated cost-effectiveness ratios lying beneath the chosen cost-effectiveness threshold can then be regarded as the probability that the intervention strategy is cost-effective.[1]

References Appendix A

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Appendix B: Brief description of selected studies

Edmunds et al.[1] performed a cost-utility analysis of HZ vaccination in England and Wales from the perspective of the health care provider. A decision analysis was used to compare a vaccinated cohort with an unvaccinated cohort and vaccination age was ranged between 45 and 80 years. The sources of the epidemiological data were all primary-care based. Because the study was performed before the SPS, vaccine efficacy was still unknown. Therefore, two different vaccine efficacy rates were explored in the model, i.e. 30% and 70% (base-case). Utility estimates were derived from literature and zoster pain was differentiated between mild and severe pain. Healthcare costs were taken from published literature and the vaccine price was assumed to be £80. Future costs and healthcare effects were equally discounted at 3%. The results presented that using a lifelong efficacy of 70%, the ICER of vaccinating 65 year olds would be £3560, which was regarded as cost-effective. Vaccination was cost-saving when cost per vaccination course was lower than £30. Vaccination was most cost-effective in the older age-groups.

Hornberger and Robertus[2] explored the cost-effectiveness of HZ vaccination for the US from the societal perspective. Costs and QALY losses were compared between a vaccinated cohort and an unvaccinated cohort containing immunocompetent persons aged ≥60 using a decision model. Epidemiological data, vaccine efficacy and utilities were extracted from the SPS. Costs were collected from various published sources and the cost of a vaccination course was varied between $50 and $500. Costs and health effects were equally discounted at 3%. The cost-effectiveness ratio remained less than $100,000 per QALY gained for every scenario where vaccine costs were less than $100, regardless of duration of vaccine efficacy. Using a $50,000 threshold, HZ vaccination was cost-effective by vaccine costs of $100 when vaccine efficacy lasted at least 20 years. Regarding to age, vaccination was more likely to be cost-effective in the younger age group (60-64 years) than in the older age-group (≥80 years).

Pellissier et al.[3] evaluated the cost-effectiveness of HZ vaccination in the US from the healthcare payer's and societal perspective. Cost-effectiveness of a vaccinated cohort aged ≥ 60 years was compared with an unvaccinated cohort using an expanded decision analytic model of Edmunds et al.[1] Epidemiological parameters of HZ incidence of the total population and the immunocompetent population were retrieved by combining data from several databases. Vaccine efficacy was modeled

using SPS data into two parameters, namely the age-dependent proportion of persons protected following immunization and the rate at which this protection declined. In the base-case scenario, vaccine efficacy was set at lifelong. Utilities were derived from the SPS and costs from the Medstat Marketscan database. Costs and health effects were equally discounted at 3%. The cost per QALY gained ranged from $16,229 to $27,609 depending on the input data (HZ incidence data from the total population or from the immunocompetent population) and the analytic perspective. Duration of vaccine efficacy has to be at least 12 years or 5 years to stay below $50,000 or $70,000 per QALY gained, respectively. Cost-effectiveness ratios were estimated to be higher for the older vaccine recipients.

Rothberg et al.[4] analyzed the cost-effectiveness in the US among individuals aged ≥60 years. Cost-effectiveness of a vaccinated cohort was compared with an unvaccinated cohort from the societal perspective using a Markov model. Epidemiological data were retrieved from published data and vaccine efficacy from the SPS. No additional efficacy to burden of illness over the efficacy against HZ was counted below the age of 70. Duration of vaccine efficacy was set at 10 years. Utilities and costs were derived from published data and the base-case vaccination cost was $149. Costs and health effects were equally discounted at 3%. Results showed that the cost per QALY gained ranged from $201,000 for patients aged 60-69 years to $75,000 for patients aged ≥70 years and the optimum vaccination age was 70 years. Vaccinating women was more cost-effective in all age-groups as compared with men. To achieve an ICER below $50,000 per QALY gained for vaccinating all adults between the age of 60 to 80, the vaccine costs had to decrease to $46.

Brisson et al.[5] performed a cost-effectiveness study of HZ vaccination in Canada from the perspective of Ministry of Health. A cohort model was used to compare vaccination of a cohort existing of individuals aged 65 years with unvaccinated individuals of the same age. The vaccination age was ranged between 50 to 80. Epidemiological data were extracted from the Manitoba physician billing claims database and hospital databases. Equal vaccine efficacy parameters as in the study of Pellissier et al.[3] were used. Quality-of-life weights were taken from a Canadian prospective study. Costs of HZ cost were obtained from Canadian sources and costs of PHN from published US sources. Costs and health effects were discounted equally at 5%. Results show that the ICER was estimated at $CAN 33,000 dollar when lifelong vaccine efficacy and a $CAN 150 costs per vaccination course were applied. Regarding to the probabilistic sensitivity analysis, vaccination between the age of 65 and 75 years was likely to be cost-effective, vaccinating at ages of 50 and 80 years likely not, when a threshold of $CAN 40,000 was used.

Najafzadeh et al.[6] compared the cost-effectiveness of a HZ vaccinated cohort with an unvaccinated cohort in Canada using a discrete-event simulation (DES) model. The cohorts existed of immunocompetent adults aged ≥60 years and the TPP's perspective was used. Epidemiological data and vaccine characteristics were derived from the SPS and vaccine efficacy was assumed to reduce to half after 15 years. Quality-of-life weights were taken from a published study performed in the US. Costs were extracted from several Canadian medical databases and cost of a vaccination course was assumed at $CAN 150. Costs and health effects were equally discounted at 5%. Results showed an ICER of $CAN 41,709 per QALY gained. Vaccinating individuals aged 60-74 years was more cost-effective as compared with >75 years. The probabilistic sensitivity analysis demonstrated that 52% of vaccination strategies resulted in an ICER of less than $CAN50,000 per QALY gained.

Van Hoek et al.[7] estimated the cost-effectiveness of vaccination against HZ in England and Wales using a Markov-cohort model. Cost-effectiveness of a vaccinated cohort consisting of elderly aged 60, 65, 70 or 75, respectively, was compared with an unvaccinated cohort of the same age from the perspective of the health care provider. Epidemiological parameters of England were derived from medical databases. Age-specific vaccine efficacy and efficacy duration were estimated by fitting a model to SPS data. In the base-case scenario, duration of vaccine efficacy was set at 7.5 years. QALY losses due to HZ and PHN were estimated by fitting a model to data of several published studies. Costs were extracted from a the general practitioners research database (GPRD) and total cost per vaccination course was assumed at £65. Costs and health effects were equally discounted at 3.5%. Results showed that cost-effectiveness of vaccination at the age of 65 was £20,400 per QALY gained. The threshold price for the vaccine was around £80-90 when a threshold of £30,000 per QALY gained was used. A scenario with a booster vaccine was substantially less cost-effective as compared with the one-dose base case. The optimum age to vaccinate was 70 years.

Annemans et al.[8] performed the first Belgian study assessing the cost-effectiveness of vaccination of elderly aged ≥50 against HZ compared with no such vaccination. A Markov-model constructed by Moore et al.[9] was used and results were presented from the third-party payer, healthcare and societal perspectives. Epidemiological data was derived from a Belgian general practitioners database and risk of PHN from the GPRD in the UK. Vaccine efficacy was obtained from the SPS and duration of vaccine efficacy was assumed at lifetime. Duration of PHN was shortened in the vaccinated group. Utilities were derived from published data from the US. Cost data were extracted from several Belgian sources and vaccination cost was assumed to be €141 per course. Costs and health effects were differentially discounted at 3% and 1.5%, respectively. Results showed that

vaccination against HZ was cost-effective from all three perspectives (ranging €6.799-€7168 per QALY gained) when an unofficial threshold of €30,000 per QALY gained was used. ICERs varied little between scenarios of different age-groups, but vaccinating was most cost-effective in the age-group 65-69 years.

Moore et al.[9] assessed the cost-effectiveness of vaccinating the elderly against HZ for the UK from the perspectives of the National Health Service (NHS) and the societal perspective. A Markov-model was used to compare the cost-effectiveness of a vaccinated cohort with an unvaccinated cohort within age-groups ranging from 50-54 years to ≥ 100 years. Epidemiological data was derived from a published study, providing UK data. Vaccine efficacy, duration of PHN and the pain-split (division of HZ/PHN cases between mild, moderate and severe pain) were taken from the SPS. In the base case, duration of vaccine efficacy was assumed to be lifelong. Utilities were derived from a published study performed in the US. Cost data from a published study were used and vaccination cost was set at £105.40 per course. Costs and effects were equally discounted at 3.5%. Results showed that vaccinating elderly ≥ 50 resulted in an ICER of £13,077 and £11,417 from the NHS and societal perspective, respectively. From societal perspective, vaccinating the age-group of 55-59 years was most cost-effective, but from the perspective of NHS this was the case at the age-group of 65-69. When a vaccine efficacy duration of 10 years was applied, vaccination of elderly aged ≥50 years was not be cost-effective anymore when a threshold of £30,000 per QALY gained was used.

Van Lier et al.[10] estimated the cost-effectiveness of vaccination against HZ for the Netherlands. The cost-effectiveness was estimated from the societal perspective using a Markov-model which was developed by Van Hoek et al.[7]. Age of vaccination was varied from 60 to 80 years. Epidemiological data was derived from a Dutch General Practitioner database and a Dutch hospital database. Vaccine parameters and QALY losses were derived from Van Hoek et al.[7] and the base-case duration of vaccine efficacy was set at 7.5 years. Costs were taken from several Dutch sources and base-case vaccination costs were assumed at €83.45 per course. Costs and health-effects were differentially discounted at 4% and 1.5%, respectively. Results showed that vaccination at the age of 70 was most cost-effective (€21,716 per QALY gained) and at the age of 60 less cost-effective (€38,519 per QALY gained). When an unofficial threshold of €20,000 per QALY gained was used, vaccination against HZ would be marginally not cost-effective. When the duration of vaccine protection was extended to 16.1 years, vaccination would be cost-effective at all ages except 80 years.

Szucs et al.[11] evaluated the cost-effectiveness of vaccinating elderly aged between 70-79 in Switzerland. A Markov-model, constructed by Moore et al.[9], was used to estimate the cost-

effectiveness for a vaccinated cohort versus an unvaccinated cohort from both the third-party payer's and the societal perspectives. Epidemiological data was obtained from a Swiss medical database and PHN parameters from published studies from elsewhere. Vaccine efficacy was derived from the SPS and in the base-case scenario no waning was assumed. Utilities were derived from a study performed in the US and cost data from a Swiss study investigating the impact of HZ and PHN on health care sources. Vaccination costs were assumed at CHF265.9 per course and future costs and health effects were discounted differentially at 3.5% and 1.5%, respectively. Results show that the cost-effectiveness was estimated at CHF25,538 per QALY gained from the TPP's perspective and CHF28,544 per QALY gained from the societal perspective. Variation of the vaccination age showed that vaccination was more cost-effective in the younger 60-69 group and least cost-effective in the 70+ group.

Bilcke et al.[12] analyzed the cost-effectiveness of vaccination against HZ in adults aged over 60 years in Belgium. A static cohort model was developed to estimate the cost-effectiveness for a vaccinated cohort compared with an unvaccinated cohort from the health care payer's perspective. Epidemiological data was extracted from a Belgian national database and the Belgian sentinel system of general practitioners. Vaccine efficacy was derived from the SPS. Duration of vaccine protection was varied from 7 years (worst case scenario) to lifelong (best case scenario). QALY loss was obtained from a published study conducted in the UK and cost parameters were derived from surveys explored in Belgium. Vaccination costs were assumed to be €111.5 per vaccination course. Costs and health effects were differentially discounted at 3% and 1.5%, respectively. Results showed that the scenario which is least in favor of vaccination showed an ICERs above €48,000 per QALY gained for every age of vaccination. The scenario which is most in favor of vaccination resulted in ICERs below €5500 for all vaccination ages. The optimum vaccination age was 60 years and vaccine price has to be reduced to €45 to obtain an ICER below €30,000 per QALY gained (unofficial Belgian threshold).

Bresse et al.[13] explored the cost-effectiveness of vaccination of elderly against HZ in France also using the model of Moore et al.[9]. Cost-effectiveness of vaccinating individuals aged 70-79 years was compared with no such vaccination and the analysis was performed from the TPP's and healthcare payer's perspective. HZ incidence rates were derived from sentinels network data, containing data from French general practitioners. SPS data concerning vaccine efficacy, pain split of HZ and PHN and pain duration of these conditions were extracted from the SPS. For vaccine efficacy, a waning rate of 4.15% was applied and after 10 years vaccine efficacy was set to zero. Cost estimates were

derived from a published study conducted in France and the vaccine price was assumed at €125. Costs and health effects were equally discounted at 4% in the first 30 years and at 2% afterwards. The study presented vaccinating individuals aged 70-79 years resulted in an ICER of €9513 per QALY gained from the TPP's perspective and €14,198 per QALY gained from the healthcare perspective. Vaccination between the age 70-79 years was more cost-effective as compared with the age-group of all over 65 years. Probabilistic sensitivity analysis demonstrated that when the cost-effectiveness threshold was set at €28,000 per QALY gained, the ICER was approximately 99% of scenarios cost-effective considering the TPP's perspective.

De Boer et al.[14] estimated the cost-effectiveness of vaccinating the elderly against HZ in the Netherlands. Cost-effectiveness of vaccinating was compared whit no such vaccination, from both the societal perspective as well as from the healthcare payer perspective and vaccination age was varied from 60 to 75. Epidemiological data was derived from published literature and utilities from a published study conducted in the US. Vaccine efficacy was obtained from the SPS as presented by Pellissier et al.[3] and efficacy duration was set at 12 years in the base-case scenario. Also the pain split and PHN duration were obtained from the SPS. Cost parameters were derived from published studies and vaccination costs was set at €93.45 per course. Costs and health effects were differentially discounted at 4% and 1.5%, respectively. Results show that vaccinating 60 year olds resulted in an ICER of €35,555 and €42,004 per QALY gained from the societal and health care perspective, respectively. Vaccination was most cost-effective at the age of 70 and vaccinating women was more cost-effective as compared to vaccinating men.

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