tion (FDA) for rifapentine and the Good Clinical Practice (GCP) standards of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Clinical trial experts reviewed the protocol and costs were assessed based on the Resource Based Relative Value Scale (RBRVS), expert opinion, and published prices for materials and services. We constructed a model that summarized costs per patient, per trial site, and per trial to implement the protocol. Entering the number of patients to be assessed, number of trial sites, number of trials, and anticipated drop out rates generated estimated costs. The model calculated the cost for all patients to complete the trial, costs associated with screening patients who drop out immediately, and savings that may be realized from patients dropping out during the trial. These figures generated lower and upper trial cost estimates. A 15% drop out rate during the trial was assumed.

RESULTS: For 850 to 1,000 patients to complete a Phase III trial, 1,176 patients will need to be screened. The estimated total cost (2000 US dollars) is between $22.3 million and $22.6 million.

CONCLUSIONS: A Phase III clinical trial for a new pulmonary TB drug will cost between $22.3 million and $22.6 million, assuming a drop out rate no greater than 15% at screening and 15% over the course of the trial.

**PIN7**

**PHARMACOECONOMIC EVALUATION OF IMQUIMOD (ALDARA) FOR THE TREATMENT OF EXTERNAL GENITAL WARTS IN A DUTCH TREATMENT ENVIRONMENT**

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OBJECTIVE: To assess the cost-effectiveness of Aldara (Imiquimod) 5% topical cream versus other therapies for the management of external genital warts (EGWs) in a Dutch treatment environment.

METHODS: An economic model is presented that utilizes a two-stage therapy sequence. Choice of initial and subsequent therapy was based on the results of a recently completed chart review of three dermatology clinics in the Netherlands. This chart review provided valuable guidance regarding treatment switching, resources used (i.e. average number of patient visits) and costs associated with the management of EGWs. Sustained clearance rates were incorporated into the economic model based on published literature of key clinical trial results. Costing was based on nationally available cost estimates for the Netherlands as costs based on chart reviews were site specific and hence were not appropriate for use.

RESULTS: Estimated average costs per successful clearance for Aldara plus cryotherapy were 1,128 DFL (€ 512) compared with 1,455 DFL (€ 660) for the next most cost-effective therapy sequence—Condyline (first line) plus cryotherapy (second line). In terms achieving the therapeutic target of 50% clearance, only sequences in which Aldara was used as first line therapy achieved this.

CONCLUSION: The results of the cost-effectiveness analysis demonstrated that Aldara (as first line therapy) plus cryotherapy (second line) was the most cost-effective therapy sequence in the Netherlands.

**PIN8**

**A COST-BENEFIT ANALYSIS OF INFLUENZA VACCINATION IN A COMPANY IN ITALY (ENI SPA)**

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OBJECTIVE: To estimate costs and benefits of a preventive influenza vaccination in a group of employees of Snamprogetti (an Eni-group company), to define a scheme of cost-benefit analysis to be used for other strategies of vaccination and in other contexts.

METHODS: In an observational study conducted from October 1999 to June 2000, 153 employees (about 10% of the whole staff of Snamprogetti) voluntarily received the vaccine, and were compared to 153 non-vaccinated employees working in the same context and matched for age and gender. The outcome was evaluated by checking absentee records from the personnel department and determining the causes, including influenza. Costs and benefits of the influenza vaccination from the Snamprogetti point of view were subsequently calculated.

RESULTS: The influenza vaccination strategy reduced absence from work by 77% and has decreased the loss of working days by 82%. The relationship between the benefits of the vaccination strategy (less working days lost) and its cost was 12.12. Convenience also becomes evident following sensitivity analysis, which considered the mean cost of a working day for the employees enrolled, and showed that the cost-benefit ratio was 9.45.

CONCLUSIONS: The results of this study suggest that implementation of an influenza vaccination strategy in Snamprogetti was cost effective. The cost-benefit analysis used in this study could also be used for other vaccination strategies and in other contexts.

**PIN9**

**COST-BENEFIT ANALYSIS OF VACCINATING HEALTHY WORKING ADULTS AGAINST INFLUENZA IN THE NETHERLANDS**

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OBJECTIVES: Influenza is a major cause of illness, productivity loss, and work absenteeism among healthy working adults aged between 25 and 64 years. This group is not
included in the national Dutch influenza vaccination program, that encompasses the elderly of 65 years and older. The objective of this study is to estimate the cost and benefits of vaccinating healthy working adults aged 25 to 64 years against influenza.

METHODS: Our cost-benefit analysis includes the direct and indirect costs associated with vaccination as well as the direct and indirect costs avoided by vaccination. The underlying model links influenza incidence to health-care resource use, work absenteeism and productivity loss. Health-care resource use was specified for general practitioner visits, hospitalizations and drugs. Clinical and economical parameter estimates were derived from published literature and Dutch registry data.

RESULTS: Vaccinating healthy working adults aged 25 to 44 years costs € 0,39 per person per year. Vaccinating persons aged 45 to 64 years saves € 1,51 per person per year. On the population level, vaccinating persons aged 25–44 years costs about € 1,4 million per year, vaccinating persons aged 45–64 years saves about € 2,3 million per year. On average, vaccinating healthy working adults saves € 0,9 million. The indirect costs prevented primarily determine the cost-benefit outcome of vaccination for healthy working adults.

CONCLUSIONS: Influenza vaccination of healthy working adults is cost saving. These findings support routine vaccination for this group, from the employer’s perspective.

DEVELOPMENT AND VALIDATION OF A 17-COUNTRY EUROPEAN PHARMACOECONOMIC MODEL: THE ONYCHOTREE STUDY

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OBJECTIVES: Toenail onychomycosis is the most common nail fungal infection. If left untreated, it can evolve into a more severe stage that can involve the matrix. The clinical management of patients remains constraining and long. In addition, relapses occur frequently after antifungal treatment. This has significant socio-economic impact. Combining topical and oral antifungals can increase cure rates and decrease treatment duration. The OnychoTree project aims at providing an evaluation tool to estimate economic consequences of the management of severe toenail onychomycosis in Europe.

METHODS: The methodology for OnychoTree development follows a rigorous stepwise design to obtain an international model, valid for use across 17 countries: 1) an extensive literature review of international data on toenail onychomycosis; 2) the design of a core clinical management-decision tree; 3) the validation and completion of the core model (treatment patterns and medical resource use) by an expert panel of 12 dermatologists from six countries; 4) expansion and validation of the model to 11 additional countries through advisory panel interviews assessing national specificities (disease management and associated costs); 5) a meta-analysis of efficacy rates from relevant clinical trials of antifungals; 6) cost-effectiveness analyses.

RESULTS: The initial common model was designed from the available international literature. The expert panel clinicians confirmed their interest for: 1) a clinical management model, and 2) cost-effectiveness evaluation including new combination therapies. They requested adaptations to reflect country-specific medical practice. After adaptation, they validated the core European pharmacoeconomic model. Advisory panel interviews confirmed these results, focusing on the need for country-specific analyses based on a common decision tree.

CONCLUSIONS: Cost-effectiveness analyses including the 17 country-specific data will be performed with the final model. These European results will make both medical professionals and the public aware of the possible improvement in health-care resource use for the management of severe toenail onychomycosis.

A COST BENEFIT ANALYSIS OF TWO ALTERNATIVE MASS IMMUNIZATION PROGRAMS WITH A CONJUGATE VACCINE AGAINST MENINGOCOCCAL DISEASE TYPE C

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OBJECTIVE: We conducted a cost-benefit analysis of two approaches to manage a regional outbreak of serogroup C meningococcal disease (MCD): 1. a planned mass immunization program (MIP) of 2,000,000 Quebec residents aged 2 months to 20 years, that would be implemented in September 2001; 2. an emergency MIP implemented at the peak of subsequent outbreaks.

METHODS: As a reference case, we used the scenario that occurred in Quebec in 1991—several targeted regional vaccination programs were implemented in an attempt to ward off a more widespread outbreak of MCD. Unfortunately, at the end of 1992, public-health authorities had to implement a province-wide emergency MIP. We assessed the benefit of the programs using epidemiological data from the previous cycle of MCD in Quebec. Benefits included the number of new MCD cases prevented by the administration of Menjugate™ and their associated hospital and societal costs due to premature mortality and related morbidity. Costs included acquisition and administration cost of the conjugate vaccine, clerical, physician and health-services costs, and those related to lost productivity. We conducted the analysis in a societal perspective assuming Quebec would face a similar epidemiological situation in 2001 as the one that started in 1991. All costs were transformed into 2001 Canadian dollars at an annual inflation rate of 3%.

RESULTS: Over a 12-month period, a planned MIP would prevent 127 new cases (18 deaths, 24 major complications) while saving $15.0 million in direct costs to