OUTCOME VALIDATION OF A SUCCINCT HPV INFECTION MODEL FOR FRANCE
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OBJECTIVE: An HPV/cancer epidemiology model has been developed aiming to be succinct in structure and data input providing valid long-term HPV infection and cancer case predictions, a first step for estimating cost-effectiveness of new HPV vaccines. METHOD: A lifetime Markov process model with one year cycle length has been selected as basic matrix and is developed in Microsoft®Excel software. The model structure describes the natural history of High-Risk HPV (HR-HPV) infections through 9 health states: No-HPV; HR-HPV without lesions; low and high grade Cervical Intraepithelial Neoplasia (CIN1 and CIN23); persistent CIN23; CC; cured CC; CC death; and overall death. A screening module (organized and/or opportunistic) simulates early detection and treatment of CIN lesions reducing their progression to CC. Two types of data-sets for data-input are created: related to the natural history of the disease (supposed to be equivalent across countries and extracted from literature or from expert opinion) and country-specific (HPV incidence, death rate, screening practice, CIN and cancer specific treatment). Outcome model validation is performed with French data comparing model predicted cervical cancer incidence and mortality rates with estimates from national cancer registries.

RESULTS: The model predicts 1.7 cases per 100,000 subjects in 20 to 24 age-group (1.3 observed); 21.3 cases in 40 to 44 age-group (19.8 observed); 17.9 cases in 75 to 79 age-group (17.2 observed). Overall the model overestimates the CC cases with only 5% (n = 3369 modeled cancer cases; 3387 observed for the year 2000). CONCLUSION: Succinct model development is able to replicate within 5% confidence the CC incidence observed. The model is a helpful tool for simulating economical consequences of HPV vaccine in those countries with paucity of data which doesn’t allow using the more complex models.

TRASTUZUMAB USE FOR METASTATIC BREAST CANCER—IS “MEDIAN TIME TO TREATMENT FAILURE” AN ACCURATE PARAMETER FOR BUDGET IMPACT ANALYSIS?
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OBJECTIVES: Budget Impact Analysis (BIA) preformed for new and expensive anti-cancer drugs should rely on precise data regarding the cost and amount of drug that would be utilized. Besides epidemiology & required doses, BIA needs to take into account the mean duration of treatment (DOT). In metastatic cancer, patients are usually treated by each line until disease progression. When reporting phase III trials, not all patients have failed treatment, and only “median time to treatment failure” is available. Therefore, BIA would rely on the median rather than the mean DOT. Five years after introducing Trastuzumab in the Israeli national formulary, we evaluated whether the original BIA based on a phase III trial, was accurate. METHODS: Clalit Health Services’ computerized database was used to determine Trastuzumab DOT in all patients that started treatment during 2000–2002. The mean & median DOT was compared to the “median time to treatment failure” (5.8 months) in a phase III trial. RESULTS: In year 2000, the median and average DOT were 6.0 months and 9.9 months, respectively (n = 132) (patients have received prior treatment with AC & T, as determined by formulary criteria). In 2001 the median and average DOT were 9.0 and 13.6 months, respectively (n = 89) (criteria were changed, and patients were only required to be pretreated with AC). In 2002, the median DOT was 11.0 months and the mean DOT was 14.4 months (n = 71). CONCLUSIONS: In “real life” patients, mean trastuzumab DOT for metastatic breast cancer was 31–65% higher than the median DOT in the same patients. Median DOT itself was up to 55% higher than reported in the phase III trial. When performing BIA for treatments of metastatic cancer, the estimation of the budget impact may be substantially higher when using the mean rather than the median value, reported in phase III clinical trials.

PRESCRIPTION MEDICATION COSTS TO PROSTATE CANCER PATIENTS: SURVEY RESPONSES COMPARED TO AN ADMINISTRATIVE REGISTER
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OBJECTIVES: Economic evaluations conducted from a societal perspective may include estimates of out-of-pocket expenses. Surveys and administrative registers offer two sources of out-of-pocket cost data for use in economic evaluations. We highlight potential problems in using questionnaires or administrative data alone. METHODS: Data are obtained by surveys and from an administrative register. Survey data include responses concerning out-of-pocket expenditure on prescription medications from men (N = 1400) who have been diagnosed as having prostate cancer prior to the 2004 survey. Register data concerning out-of-pocket expenditure on physician-prescribed medications are available for the survey population for pertinent time periods from the Finnish Social Insurance Institution. Register data and questionnaire data are linked using unique personal identification codes. Statistical comparison of these sources of estimates is performed using t-tests. RESULTS: The survey-based estimate of mean out-of-pocket expenditure on prescription medications from men (N = 1400) who have been diagnosed as having prostate cancer prior to the 2004 survey. Register data concerning out-of-pocket expenditure on physician-prescribed medications are available for the survey population for pertinent time periods from the Finnish Social Insurance Institution. Register data and questionnaire data are linked using unique personal identification codes. Statistical comparison of these sources of estimates is performed using t-tests. RESULTS: The survey-based estimate of mean out-of-pocket expenditure is €38 and the difference between the two estimates of mean out-of-pocket expenses is statistically significant at the 5% level. We find that, performing imputation for unit and item non–response in the survey database and for non–inclusion in the administrative register, the survey–based estimate becomes 252€ and the register–based estimate becomes 255€—no longer a statistically significant difference. CONCLUSIONS: The problems of recall error and non–response can complicate the estimation of out-of-pocket expenditure using survey methodology. High–quality public sector administrative registers can serve the information needs of health economic evaluations. However, register–based information can also be usefully supplemented by questionnaire responses and vice versa.

THE ECONOMIC VALUE OF INNOVATIVE TREATMENTS OVER THE PRODUCT LIFE CYCLE: THE CASE OF TRASTUZUMAB
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OBJECTIVES: Most pharmacoeconomic evaluations use indication-specific models based on clinical trial data projected over a lifetime horizon for a typical patient. This study estimates the incremental cost-utility ratio (ICUR) and the aggregate economic value over the product life cycle considering multiple indications using trastuzumab (H, Herceptin®) for both metastatic (MBC)