## A450

evaluations is typically not long lasting. We investigated the major factors affecting the "expiration date" of economic evaluations using conjugate meningococcal vaccination strategies as case example. METHODS: In March 2007, we conducted a systematic literature review of journal articles, based on a comprehensive key-word based search in generic (PUBMED, EMBASE) and specialized electronic databases (HEED, NHS EED), accompanied by manual searches of specific journals. The applied methodology in the identified studies was compared and matched to the respective national guidelines for economic evaluation. The current external validity of the study results and possible adjustments for its improvement were examined. **RESULTS:** A total of six published economic evaluations of conjugate meningococcal vaccination strategies were found. Overall, they showed that the investigated vaccination strategies were cost-effective, especially the ones targeting children at approximately age 1. Adherence of the evaluations to the respective guidelines was high except for the discount rate. The latter was however directly related to the recent change in Dutch and UK recommendations. Sensitivity analysis was available for many factors, inclusive the discount rate allowing the estimation of the impact of those recent changes. Similarly, the effect of new findings about the vaccination protection duration and herd immunity could also be estimated for those evaluations that included those factors in their sensitivity analysis. These were however scarce. CONCLUSION: An extensive sensitivity analysis for all important factors that might change over time can extend the expiration date of economic evaluations. Ultimately, user-friendly and highly flexible models available on the internet might be the best way to transfer study results over time.

### **INFECTION**—Patient Reported Outcomes

#### A CROSS-SECTIONAL VALIDATION OF THE MINI-HIV QUESTIONNAIRE

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**OBJECTIVES:** The purpose of this study was to validate crosssectionally the MINI-HIV questionnaire in HIV patients treated with saquinavir in Spanish hospitals. METHODS: Crosssectional observational post-launch and multicentre study. HIV Patients over 18 years, who were under HAART with Saguinavir. One visit was carried out. Socio-demographic and clinical variables (symptoms, time since HIV diagnosis, CDC stage, CD4 and viral load), treatment adherence (GEEMA questionnaire), a question about general health status and the specific QoL questionnaire Mini-HIV (0 = better QoL; 100 = worse Qol) were collected. RESULTS: A total of 948 patients were included. Mean age (SD) was 42 (8.62) years. Mean (SD) time since diagnosis was 11.3 (5.6). A total of 36.1% were in Stage C of CDC. Mean score (SD) obtained in Mini-HIV was of 30.2 (17.8). A total of 64.9% had bad Qol (cut of point under 22 score). Correlation between Mini-HIV score and CD4 was low (-0.134) although it was significant (p < 0.01). In patients with detectable viral load mean (SD) of MINI-HIV score was lower than in patients with undetectable viral load (32.9 (18.1) vs. 28.8 (17.5); p < 0.01). QoL was worse in patients who presented symptoms in the last two weeks or that presented other concomitant disease (p < 0.01). The more frequent symptoms were weakness, anxiety, insomnia and depression. There was no difference in MINI-HIV

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score according to the form of administration (BID vs OD). Internal consistency of MINI-HIV was of 0.914 (higher than 0.7 theoretical). General health status was 'very good' in 42.3% of the patients. MINI-HIV scores were related to the general health status question (p < 0.01). Non adherent patients obtained higher scores (worse Qol) than adherent patients (p < 0.01). CONCLUSION: The results of this study show that Mini-HIV has good psychometrical properties and can be a good tool for monitoring treatment effectiveness and health states of HIV patients.

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### DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF THE VACCINEES' PERCEPTION OF INJECTION (VAPI) QUESTIONNAIRE TO ASSESS SUBJECTS' ACCEPTANCE OF INFLUENZA VACCINATION

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<sup>1</sup>Sanofi Pasteur, Lyon, France, <sup>2</sup>Mapi Values France, Lyon, France **OBJECTIVES:** To develop and validate a self-administered questionnaire assessing subjects' perception and experience with injection, and their acceptance of injection site reactions (ISR) including pain following influenza vaccination. METHODS: Following a literature review, the VAPI questionnaire was simultaneously developed in US English, German and French, based on interviews of subjects (n = 33) vaccinated intramuscularly (IM) or intradermally (ID) with an influenza vaccine. Items were generated from subjects' verbatim, comprehension tested with elderly and adult vaccinees (n = 23); then a linguistic validation was done. The initial, 44 item-version of the questionnaire was administered 21 days after vaccination to subjects from Belgium, France, Spain, the UK, Germany and Italy who were participating in clinical trials comparing ID versus IM influenza vaccination.Scale construction and item reduction were conducted using principal component and multitrait analyses with 549 English subjects. Psychometric validation of the final questionnaire was performed per country (n = 5,543) and included: 1) construct validity by item convergent and discriminant validity, 2) internal consistency reliability by Cronbach's alpha and 3) clinical validity by describing the scores according to ISR severity. RESULTS: After item reduction, the final questionnaire comprised 4 multiitem dimensions ("bother"; "arm movement"; "sleep"; "acceptability") grouping 16 items plus 5 individual items (anxiety before vaccination; bother by pain during vaccination; satisfaction with the injection system; anxiety of being vaccinated next year; willingness to be vaccinated again). Item convergent and discriminant validity was confirmed for all scales in most countries. Multi-item dimension internal consistency reliability was good to excellent for all countries (Cronbach's alpha ranging from 0.73 to 0.94), except for the "sleep" dimension in Italy (0.68). Dimension scores demonstrated good clinical validity: greater severity of ISR was associated with higher scores. CON-CLUSION: The self-administered VAPI questionnaire is valid and reliable. Therefore, it is a promising tool for the assessment of the acceptance of a vaccine injection system.

### **METHODS & CONCEPTS**

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### COMPARISON OF EMR DATA TO US NATIONAL DATA Oderda GM<sup>1</sup>, Brixner D<sup>2</sup>, Lieberman M<sup>3</sup>

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**OBJECTIVES:** Compare data from a large national EMR in the US to national published data. **METHODS:** Data from GE