OBJECTIVE: To optimize the design of a large, complex, proposed trial, and to estimate the power / precision / sample-size / effect-size relationships of that trial, by means of a realistic Monte-Carlo simulation. The proposed trial would evaluate the third-party-payer cost-effectiveness of using standardized combination regimen kits vs. current practice to manage and treat acute sinusitis. Availability of standardized kits could potentially simplify non-prescription product selection, improve adherence, and prevent unnecessary antibiotic prescribing. **METHODS:** Using the R programming language, we simulated all essential operational features of the proposed trial—presentation of patients with bacterial or viral sinusitis, randomization to usual care or one of two standardized kits; effectiveness of the first-round regimen, and prescription (if necessary) of second-round therapy. Using best available literature values for bacterial and viral sinusitis prevalence, distribution of prescription and OTC medication costs, and response rates to various regimens, and using various postulated sample sizes and kit costs, 1000 simulations of each scenario were run. Cost-effectiveness, power, precision, and sensitivity analyses were conducted on the simulated outcomes. **RESULTS:** Empirical models of power as a function of effect size, sample-size, response rates, and kit costs were fitted to the simulation results; these were used to create interactive graphical displays showing the power-vs.-sample-size curves, and precision-of-cost-estimate curves, for any response rate and kit cost. The ease of manipulation of these graphs permitted the rapid exploration of many alternative scenarios, leading to an optimized study design. **CONCLUSIONS:** The simulation analysis of this complex trial permitted not only the reliable estimation of power and precision for a complex study, but also provided a framework for thinking rigorously and quantitatively about the design of the study, and for acquiring and utilizing available data required for the optimization of the study.

IN3

COSTS OF DELIVERING ADULT INFLUENZA VACCINATION IN NON-TRADITIONAL SETTINGS

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OBJECTIVES: To measure the costs of delivering inactivated influenza vaccinations to adults in non-traditional settings. Non-traditional settings may represent an opportunity for boosting influenza immunization coverage rates for recommended adults. **METHODS:** We collected data through telephone surveys with representatives of organizations that conduct mass vaccination clinics for influenza vaccination in a variety of non-traditional settings, such as employer sites, retail stores and pharmacies (n = 7) and pharmacies that use pharmacists to deliver vaccinations (n = 5). Telephone interviews were conducted between January and April, 2004. Data on costs of vaccine dose, supplies, clinical and administrative labor costs, overhead, promotion/advertising, number of vaccinations delivered, and waiting and vaccination time for vaccine recipients were collected. Time costs were calculated using 2003 average US wage data. Primary outcomes were total costs per vaccination delivered including and excluding recipient time costs. **RESULTS:** Survey participants delivered 4.5 million doses of influenza vaccine through mass vaccination clinics and 300,000 doses via pharmacists for the 2003–2004 influenza season. Mean total costs per vaccination, not including time costs, were estimated to be $17.04 (95% CI: $14.43–$19.66) for mass vaccination clinics and $11.57 (95% CI: 9.79–$13.35) for pharmacists. If time costs were included, total vaccination costs were $20.52 (95%CI: $17.38–23.66) for mass vaccination clinics and $15.20 (95%CI: $12.21–18.20) for pharmacists. The largest single component of costs was the cost of the vaccine dose (range = $6.75–$8.95). Mean waiting and vaccination times for the recipient were estimated to be 12 minutes in both settings. **CONCLUSIONS:** Compared to published estimates of delivering influenza vaccination through scheduled visits in the traditional physician office setting of $21.34–$50.43 (Coleman MS et al., 2005), costs of delivering influenza vaccination may be lower in non-traditional settings. Data on costs of vaccination by specific setting type are required for evaluating the cost-effectiveness of delivering influenza vaccination in non-traditional versus traditional settings.

IN4

COST EFFECTIVENESS OF HIV TREATMENT INNOVATIONS OF GREATER EFFICACY THAN HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART)

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OBJECTIVES: We evaluated the long-term clinical benefits and costs associated with HAART from a societal perspective with respect to its current efficacy, and explored the cost-effectiveness of therapies of greater efficacy. **METHODS:** A Monte Carlo Markov model was created to simulate the treatment sequence and disease progression and costs for a hypothetical cohort of 10,000 asymptomatic, treatment-naïve patients initiating HAART with CD4 cell count of 200–350 cells/μL and viral load of 100–55,000 RNA copies/mL. The model's treatment states are two distinct HAART regimens, a rescue regimen, and no antiviral treatment. During each yearly cycle, the patient has either therapeutic success or failure with no AIDS-related infections, AIDS, AIDS-related death, or death from other causes, the probabilities of which (except other cause death) are dependent on CD4 cell count. Model parameters were derived from published literature and data from the Multicenter AIDS Cohort Study. Assuming future treatment strategies improve upon the utility of HAART by increasing the probability of treatment success by at least 10%, we estimate mean costs and quality adjusted life years (QALYs) of HAART and future treatments. **RESULTS:** Mean costs of non-HAART (modeled for comparison), HAART and rescue regimens are $7739, $14,468, and $34,196, respectively. Mean costs of AIDS and AIDS-related death are $28,772 and $67,533, respectively. Mean survival times are 5.19 and 2.55 years (4.01 and 1.92 QALYs) for the HAART and non-HAART cohorts, respectively. Mean discounted (at 3%) lifetime cost of HAART was $171,313. The ICER of HAART over non-HAART was $22,570/QALY. Future treatment strategies of 10% greater efficacy lead to a mean of 0.43 QALYs gained at a cost of $5749 ($13,318/QALY). Future treatment costs <120% of current HAART, have an ICER of <$0,000/QALY. **CONCLUSIONS:** Even modest increases in treatment success and cost result in additional QALYs well below the generally accepted threshold.

Quality of Life

QL1

IS RELIEF WORTH THE RISK? RISK-BENEFIT PREFERENCES FOR TREATMENTS FOR VASOMOTOR SYMPTOMS

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OBJECTIVES: To derive valid estimates of women's willingness to accept elevated fracture, cardio-vascular and cancer risks in return for the benefits of treatments that reduce vasomotor symptoms. **METHODS:** This study used a pretested stated-

choice instrument to elicit women's tradeoff preferences for various treatment attributes, including both benefits and risks for therapies to relieve vasomotor symptoms. The survey was administered to 500 US women between the ages of 46 and 60, randomly sampled from a large internet consumer panel. Two survey versions were administered to split samples. The versions were identical except that risk descriptions incorporated relative risks in one version and absolute risks in the other version. Ordered-probit importance weights for various health states and risks were estimated from the resulting tradeoff data. **RESULTS:** We found that the risk description did not affect ordered-probit estimates of respondents' preferences for risk of fracture and heart attack, but did affect preferences for the risk of breast cancer. Subjects who received the relative-risk versions indicated that a decrease in risk of breast cancer from 3.9% to 2.3% was 64% more important than subjects who received the absolute-risk version. Conversely, subjects who received the absolute-risk version were more concerned about relieving vasomotor symptoms. Relieving the severity of hot flashes was 44% more important, reducing the frequency of hot flashes was 40% more important, and reducing the frequency of night sweats was 50% more important for subjects who received the absolute-risk version than for subjects who received the relative risk version. **CONCLUSION:** Although health professionals presumably interpret clinical relative-risk results in the context of the base prevalence of a condition, laypersons often do not have access to base-rate information. Our results suggest that more careful characterization of adverse-event risks is important in helping women make fully informed choices among alternative treatments for vasomotor symptoms.

QL2

NEW WEIGHTS FOR OLD: A SCALE OF VALUES FOR EQ-5D HEALTH STATES

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OBJECTIVES: EQ-5D is one of the most widely used index measures of health-related quality of life. Ten years have passed since the first UK national survey that established preference weights for EQ-5D health states. That protocol elicited values for 45 of the 245 possible EQ-5D health states. Values for the remaining health states were interpolated from estimation models based on the values for directly observed states. The process of model construction and testing was onerous and labour intensive. Estimated values remained largely untested as replication studies are virtually non-existent. This paper reports on an alternative approach in which values for *ALL* health states are elicited. **METHODS:** The standard questionnaire used to value EQ-5D health states records VAS ratings on a 0–100 scale, for 16 health states presented as two groups of eight on consecutive pages. The logically best and worst health states are repeated on each page. A value for dead is also elicited in each questionnaire. For this study, 21 versions of the questionnaire were designed, each presenting 14 different states. Questionnaires were mailed to 1100 individuals selected randomly from the electoral registers of England and Wales. **RESULTS:** A response rate of 62% was achieved (n = 685). Mean VAS scores from this survey were similar to those elicited ten years earlier although the value for dead was 45% higher than its predecessor. A smooth, well-behaved set of values for all 245 states was derived using OLS regression ($r2 = 0.974$, $p < 0.001$). Transformed to a 0–1 scale, values were systematically higher than the corresponding TTO weights used as standard in NICE appraisals reporting EQ-5D. Only 12 states demonstrate negative values. **CONCLUSIONS:** Traditional interview-based procedures are costly. This study demonstrates the feasibility of postal survey methods and simultaneously poses a dilemma for end-users. Are contemporary VAS–based values preferable to decade old TTO-based values?

QL3

(For QL3 see page 337)

QL4

THE CONTENT VALIDITY OF CLINICIAN DERIVED PATIENT REPORTED OUTCOMES (PRO) MEASURES: THE ROLAND MORRIS DISABILITY QUESTIONNAIRE

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OBJECTIVES: The FDA currently requires patient interviews in the process of developing a new PRO measure. In the past, many questionnaires were developed based solely on clinician expertise and patient involvement in the creation of items was non-existent. In order to ensure existing questionnaires are accepted by the FDA, it is necessary to confirm the content validity of