compare patient-reported outcomes in two statins (Statin A and Statin B). Medwatch is the Food and Drug Administration’s (FDA) program for reporting serious reactions with drugs and other medical products. Consumer reports are an increasing number of those drug safety reports and through March 30, 2003, make up more than 27% of the total Medwatch reports.

**METHODS:** The QSCANTM software was used to compare the consumer spontaneous reports of two statins (Statin A and Statin B), using a signal detection methodology, the proportional reporting ratio (PRR). The two statins were also individually compared to the class of statin drugs. **RESULTS:** Statin A had 32,371 consumer reports of adverse events, and Statin B had a total of 21,895 consumer reports through the first quarter of 2003. Report dates were comparable for the two statins. Compared to Statin B, Statin A had a significantly higher proportion of reports for arterial occlusion, cardiac arrest, increased blood cholesterol, coronary artery surgery, transient ischemic attack, and aggravated condition. Statin B had a significantly higher PRR for burning sensation (within nervous system disorders), diabetes mellitus, and decreased blood pressure. The significantly elevated PRRs for Statin B persisted when compared to all other statins, whereas Statin A appeared similar to the rest of the statin class for these particular adverse event reports.

**CONCLUSIONS:** Using drug safety signal detection data mining technology of consumer-driven spontaneous reports, it is possible to identify possible areas of drug differentiation between two drugs or a single drug and an entire drug class. Consumer Medwatch reports are spontaneous drug adverse event reports that are voluntarily submitted by the consumer and may be an informative source of real-life patient reported outcomes.

**TRAINING REGULATORY AGENCIES IN PRO EVALUATION: THE WORKMATS EXPERIENCE**

**Acquadr C**, **Lobo-Luppi L**, **Chassany O**

1Mapi Research Institute, Lyon, France; 2Hôpital Saint-Louis, Paris, France

A survey of European Regulators conducted by the ERIQA Group evidenced the need of training on HRQL and PRO. To meet this need ERIQA in collaboration with the Cochrane HRQL Methods Group proposed an Educational Program on PRO and HRQL using the Workmats, designed for interactive learning within a group to facilitate the understanding of key concepts. In 2002 and 2003, regulators were trained in France (AFSSAPS, ANAES), in Belgium (INAMI) and in the US (FDA). Members of the Cochrane Collaboration were also trained during the Stavanger and Barcelona colloquia. **OBJECTIVES:** To assess the relevance and the impact of the Workmats training from the regulators perspective. **METHODS:** We provided an evaluation form at the end of each session. Seven questions were asked addressing the content, the format and the attitude towards PROs in the future. **RESULTS:** Eighty persons were trained: thirty-two members of the Cochrane Collaboration and 48 regulators. To Question 2: Did you learn some useful information? Ninety-seven and one-half percent answered Yes. To Question 3: Did the workshop come up to your expectations? Ninety-one and one-third percent answered Yes, 6.2% No and 2.5% did not answer. To Question 6: will this training change your way of evaluating files? Ninety-one and three-fifths percent did say yes, 21.3% said maybe, 3.7% said No and 6.3% did not answer. **CONCLUSION:** Workmats proved to be a useful training tool by providing basic information on PROs and enabling regulators to better understand the field. The fact that 91.6% of the attendees said that this training might change their way of reviewing files and 90% might recommend the session to colleagues encouraged us to plan sessions in 2004 in other European countries and the US.
Americans (n = 441), African Americans (n = 344), Jamaicans (n = 41). Each person was given one of three hypothetical health states. Variables collected included: age, gender, race/ethnicity, current and scenario HRQOL (on Likert and Visual Analogue Scale (VAS)), TTO scores, and importance of religion. Chi square and Mann-Whitney U tests were used to analyze the data.

RESULTS: Out of 823 participants, 83% were traders and 17% were non-traders. Traders had significantly higher proportions of females (59%, p = 0.023), US whites (56%, p = 0.020), and those who had finished college (30%, p = 0.013), whereas non-traders had significantly higher proportions of males (52%, p = 0.023), US blacks (52%, p = 0.020) and those who had only finished high school (79%, p = 0.013). Non-traders had significantly lower average rank for age (p = 0.008) and higher average rank for importance of religion (p = 0.034) than traders. There was no significant difference between traders and non-traders for current HRQOL (Likert and VAS), but non-traders had significantly higher average rank for scenario HRQOL than traders (p < 0.0001). CONCLUSIONS: Younger age, male gender, completed high school but no college education, and higher importance of religion were significantly associated with being a non-trader. Non-traders perceive HRQOL associated with health states as better compared to traders. Future studies employing multivariate methods should be undertaken to determine the predictors of being a non-trader.

PMD22

PATIENT PREFERENCES FOR COMPUTER ASSISTED DATA COLLECTION AT THE CLINICAL INTERFACE
Shaya FT1, Finkelstein J2, Arora M2, Samant N1, Scharf S1
1University of Maryland, Center on Drugs and Public Policy, Baltimore, MD, USA; 2University of Maryland, Chronic Disease Informatics Group, Baltimore, MD, USA

OBJECTIVES: The objective of this project was to create and test the acceptability and efficiency of a universal platform for an automated survey collector in order to develop and implement a rapid, interactive computer-based collection of patient data. METHODS: The mean age of the participants in this study was 52 (range 35–69). The Automated Survey Collector (ASC) tool was first developed to be used as a universal platform. Using qualitative analysis, this interactive data collection tool was then used for pilot testing a TabletPC in patients with limited computer experience. The study implemented the SF-12 Health Survey (SF-12) and Health Utilities Index (HUI) self-administered, quality of life questionnaires. Patients were given both computer and paper versions of the survey, in random order. Data on demographics and prior computer were also collected. RESULTS: Of the 20 patients enrolled, 73% were male, 55% had no employment and 82% had no previous computer experience. The qualitative analysis of the system acceptance showed that it can be successfully implemented. All patients stated that they prefer using ASC as a survey tool rather than the paper version, and that it was “easy to use”. The majority of patients (96%) claimed that operating ASC “was not complicated at all” and 92% felt that it was “very easy to navigate through the program”. In addition, time to complete the survey was respectively 28% and 6% shorter for the computer versions of HUI and SF-12. CONCLUSIONS: This pilot project showed that the development and implementation of a universal platform, the ASC, can have a successful implementation process on the basis of a TabletPC in a population with minimal computer experience. The TabletPC is being explored as a feasible alternative for effective data collection in clinical trials and engineering into the workflow at the point of service.

PMD23

WHAT IS THE VALUE OF SOCIAL VALUES? THE USELESSNESS OF ASSESSING HEALTH-RELATED QUALITY OF LIFE THROUGH PREFERENCE MEASURES
Prieto L1, Sacristán JA2
1Lilly S.A, Alcobendas, Madrid, Spain

The use of preference-based measures in the evaluation of health outcomes has extended considerably over the last decade. Their alleged advantage over other types of general instruments in the evaluation of health related quality of life (HRQOL), supposedly lies in the fact that preference measures incorporate values or utilities that reflects the value of social preferences through health states. OBJECTIVES: The objective of this study was to determine whether the use of social preference weights or utilities makes any real difference when calculating scores for the Euroqol (EQ5-D) questionnaire, a HRQOL preference-based measure. METHODS: Responses to the EQ5-D of a sample of 10,972 patients from 10 countries enrolled in an observational study of the treatment of schizophrenia in Europe were used for this purpose. Two different methods of scoring the EQ-SD where compared: “weighting the items” of the questionnaire through the UK official weight coefficients, and “non-weighting the items”. Pearson’s, Spearman’s, and 2-way mixed parametric intraclass correlation coefficients were used to estimate the association of the scores obtained in both ways. RESULTS: The association between weighted and unweighted Euroqol scores was extremely high (Pearson’s r = 0.91), as was the association between their ranks (Spearman’s r = 0.93). The intraclass correlation coefficient obtained (0.89) also suggested that the concordance between the score distributions was prominent. CONCLUSIONS: A non-weighted approach to score the EQ5-D is enough to explain a high proportion of variance in scores obtained through the use of utilities. The differential contribution of weights based on population preference values is therefore minimal and, in our opinion, negligible.

PMD24

EXPECTED VALUE OF SYMMETRY OF INFORMATION: A FRAMEWORK FOR ASSESSING THE POTENTIAL VALUE OF INDIVIDUALIZING CARE BASED ON PATIENT PREFERENCES
Basu A, Meltzer D
University of Chicago, Chicago, IL, USA

OBJECTIVE: To assess the potential value of individualizing care based on patient preferences. Physician-patient interaction often involves asymmetry of information. Efforts to facilitate communication between physician and patients aim to overcome this asymmetry of information in order to improve patient welfare, but there is an important need to quantify the value of such efforts. METHODS: In this presentation, we introduce the concept of expected value of symmetry of information (EVSOI). This represents the potential value of providing physicians information on the preferences of individual patients, as reflected, for example, in parameters such as QOL weights. We also show how EVS0I varies with insurance structures that do not provide incentives to internalize relative costs of treatments. We illustrate this theory by calculating the EVS0I for physicians making treatment choices for 65–69 year old prostate cancer patients. RESULTS: Using a prostate cancer decision model, we find the annual EVS0I for 65–69 year old patients in the US is $529 million using a threshold of $100,000/QALY when physicians maximize net health benefits. Even when physicians only maximize health benefits—that is they fail to internalize relative costs of treatments—EVS0I remains to be quite large. CONCLUSIONS: The value of information on patient preference is large, even when costs are not internalized. Future studies should