Questionnaire (FSQ). Analyses were based on differences between baseline and final measures.

RESULTS: Significant differences (p < 0.05) in FSQ subscores were found in Basic ADLs, Intermediate ADLs, and Mental Health, for both pramipexole and bromocriptine compared with placebo. Pramipexole patients scored significantly higher than placebo patients, while bromocriptine patients did not, on FSQ Intermediate ADLs, Usual Activity Days Reduced, and EuroQol VAS. FSQ and EuroQol scores declined with increasing PD severity, as assessed by H&Y on FSQ domains—Basic ADLs, Intermediate ADLs, Social Activities, Quality of Interaction—and on FSQ single items—Days Cut Down on Usual Activities Due to Illness/Injury and Satisfaction with Sexual Relationship, as well as the EuroQol VAS.

CONCLUSIONS: The EuroQol VAS and some domains/items of the FSQ were sensitive to drug treatment. An inverse relationship was revealed between EuroQol VAS scores and some FSQ scores and PD severity.

**OBJECTIVE:** With the increase of QoL assessment in clinical trials, it is necessary to have cross-culturally valid instruments to pool data across countries. The FAMS, a 59-item instrument designed in US English, assesses six domains of multiple sclerosis.

**METHODS:** Prior to use in an international trial, the FAMS needed to undergo cross-cultural adaptation in nine languages. This involved the recruitment of a QoL specialist in each target country. Two independent forward translations were produced by native speakers, reconciled and then back-translated into English. The translations were tested for comprehension in a sample target population, compared and internationally harmonized. The developer clarified concepts underlying each item. Translation problems involved finding conceptual equivalents of typical US expressions and the response categories. For example, a literal translation of the term “social activity,” referring to humanitarian work in certain languages, required a descriptive equivalent. Translating “getting around in public places” necessitated lengthy descriptions in certain languages to retain the original concept. The neutral term “condition” could not be retained in certain translations, where a reference to “health state” or even “illness” was the best compromise. Patient testing showed that a response option “not applicable” was lacking and that answers should refer more clearly to the introductory sentence. To harmonize with the validated original, however, no changes were made in the response categories.

**CONCLUSIONS:** Before use in an international trial, rigorous cultural adaptation was essential in producing cross-culturally valid language versions. The integration of changes to the responses in an updated form of the instrument might require further validation. Further responsiveness data will be generated by the clinical trial. Ideally, initial instrument design should include international input.

**IMPACT OF A COST-SHARING DRUG INSURANCE PLAN ON DRUG UTILIZATION AMONG INDIVIDUALS RECEIVING SOCIAL ASSISTANCE**

LeLorier J, Blais L, Couture J, Rahme E
Centre de recherche, Centre hospitalier de l’Université de Montréal, Campus Hôtel-Dieu, Québec, Canada

**OBJECTIVE:** In August 1996, the Régie de l’assurance-maladie du Québec (RAMQ) introduced a new drug insurance plan for all residents of the Canadian province of Québec. Before this insurance plan, individuals receiving social assistance had all their medications paid for by the RAMQ. Now, they have to pay up to $50 per quarter for their medications in terms of deductible and co-insurance. Concerned that this financial constraint could have an impact on the use of medications, we investigated whether the consumption of three classes of medications (neuroleptics, anti-convulsants, and inhaled corticosteroids) had been modified after the new drug plan was introduced.

**METHODS:** Using time series analysis and the computerized databases of the RAMQ, we analyzed the variation in the number of prescriptions dispensed per month for each drug class from August 1992 to July 1997.

**RESULTS:** Users of inhaled corticosteroids were the most affected, with a statistically significant decrease of 28% in the number of dispensed prescriptions for the 11 months following the inception of the drug plan (August 1996 to June 1997) as compared with the same period 1 year before. For the same period, we expected an increase of 9% according to the trend seen from August 1992 to July 1996. For users of neuroleptics and anti-convulsants we found a 1% decrease for each, expecting increases of 7% and 8%, respectively.

**CONCLUSIONS:** Following the introduction of the Quebec drug plan, individuals receiving social assistance significantly decreased their consumption of inhaled corticosteroids, medications that are considered to be effective and essential.