substance of the wide range of problems, heterogeneous populations, and differing circumstances faced by decision-makers has yet to be justified.

FEASIBILITY OF A DATABASE APPROACH TO ADHERENCE WITH OSTEOPOROSIS THERAPY

Garfield FB¹, Caro JJ¹, Naujoks C²
¹Caro Research Institute, Concord, MA, USA; ²Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: Clinical trials have demonstrated that treatment can reduce the risk of osteoporosis-related fractures in women over 50 years by 40%. The benefits of treatment may be much lower due to lack of adherence to treatment. Up to 20% of chronically ill patients fail to initially fill their prescriptions, and 50% are noncompliant after one year. We evaluated the feasibility of using a database to estimate the relation between the occurrence of fractures and adherence to osteoporosis medication in actual practice.

METHODS: Major issues that were examined included: whether there were sufficient subjects who received osteoporosis medication in the database; whether fracture risk can be estimated in this population; how to determine whether a subject was covered for a given period based on dispensing rather than prescribing data; when a dispensing gap indicated non-persistence.

RESULTS: A community database of seven linked files from Saskatchewan covering over 99% of its 1.1 million residents was judged sufficiently large: 6,165 females older than 45 were diagnosed in 2000 as ICD9 code 733, which includes osteoporosis. Bisphosphonates were added to the formulary in 1996. In 2000, 10,720 patients filled prescriptions for the most widely used bisphosphonate and 33,585 filled prescriptions for conjugated estrogen. Physicians or hospitals treated 12,765 females for fractures. Adherence data were not available. A logical algorithm was developed to determine persistence. It combined information on minimally effective dose and maximum daily dosage with quantity, dose, dispensing date, drug type, and tablet scoring, allowed for accumulation of medications for later use, and corrected for hospitalizations.

CONCLUSIONS: The relation of fractures to adherence with osteoporosis therapy can be studied through analysis of this database using the algorithm.

A COMPARISON OF EQ-5D TIME TRADE-OFF VALUES OBTAINED IN GERMANY, UK AND SPAIN: COULD THERE BE ONE EUROPEAN EQ TARIFF?

Busschbach JJ
Erasmus University, Rotterdam, Netherlands

OBJECTIVES: More than 40 EQ-5D have been evaluated using a standardized time trade-off (TTO) protocol in large-scale samples of the general public from the United Kingdom (N = 3395), Spain (N = 979), and Germany (N = 339). This has created the first opportunity to perform a large-scale comparison of TTO values between countries. This manuscript reports the mutual efforts of several research groups within the EuroQol Group to make such comparisons.

METHODS: Variation between the samples with respect to background variables was controlled by multilevel analysis.

RESULTS: There are differences in TTO of health states: the Spanish TTO values resemble the British, but the German values are higher. The differences in TTO values are larger than the small differences found in similar international comparisons of VAS-based valuations. The differences found in the TTO can be explained in part by differences in the distribution of background variables. These results suggest that health is valued differently by the three populations when measured using TTO, although the differences are small. The differences found seem to be driven by differences in the proportion and the magnitude of negative health-state valuations. These
TO TRANSLATE OR TO ADAPT — 
WHAT DO THE QUESTIONS MEAN?
Doward LC, McKenna SP, Whalley D
Galen Research, Manchester, UK

OBJECTIVES: It is commonly assumed that the gold standard method for producing new language versions of patient-completed outcome measures is to translate using back-translation. This paper will demonstrate that translation alone is insufficient and that back-translation is an inherently flawed methodology.

METHODS: Literature review.

RESULTS: Back-translation fails to take account of the complexity of nuances and meanings inherent in language. While we might get back to where we started, it does not imply that we have traveled by the appropriate route. Back-translation can only succeed where straightforward semantic and conceptual equivalents exist in the target language. In such a case, the method is likely to have been an unnecessary expense. A further problem is the reliance on bilinguals. Their social and health status are likely to be higher than average, making them unrepresentative of the patient population. Thus, their use should be restricted to producing a first draft translation. This translation then needs to be assessed by people more typical of the average patient participant, working in their own language. The acceptability of this final version also needs to be tested with relevant patients to confirm comprehension and acceptability. However, adaptation involves both the translation and psychometric testing of an instrument for a new culture. It remains necessary to test the psychometric properties of the translation formally before it is used in a trial. The new version should be shown to have acceptable reproducibility and construct validity. Item response theory should also be applied to ensure that cultural response bias does not exist.

CONCLUSIONS: Back-translation by bilinguals cannot guarantee that a translated questionnaire will be acceptable to the target audience. Translation alone is not sufficient to ensure that the new language version is suitable for use in a clinical trial.

VALUATION OF INFORMAL CARE
van den Berg B
Erasmus University Rotterdam, Rotterdam, Netherlands

OBJECTIVES: The aim of our research has been the valuation of informal care. Informal care plays a substantial role in the total care provided to patients with chronic diseases. However, at this moment informal care is hardly incorporated in economic evaluations of health care. Especially the combination of the costs (time invested and household expenditures) and effects (health-related quality of life of informal care giving) is innovative.

METHODS: The data were collected by mailed questionnaires to primary informal caregivers in an evaluation of Dutch integrated stroke service experiments, at two moments in time. The sample size is 217 informal caregivers (two months after stroke) and 158 caregivers (six months after stroke). We used a questionnaire including a range of items on different informal care tasks. Health related quality of life was measured with the EuroQol (EQ#64979; 5).