satisfaction of inpatient and outpatient setting are influenced by the different variables. The disease cure is enough to determine the whole satisfaction in inpatient. But in outpatient setting, other than the variable of symptoms relieved, there are more variables influenced the patient satisfaction. However, the other medical process such as waiting time for several stages, patient privacy, patient right, informed consent and so on did not influence the patient satisfaction.

**PM C48**

**UPDATE OF TRENDS IN THE INCLUSION OF PATIENT-REPORTED OUTCOME (PRO) DATA IN APPROVED DRUGS LABELING BY FDA AND EMEA**

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**OBJECTIVES:** The PROlabels database (www.mapi-prolabels.org) was developed to provide easy access to Patient-Reported Outcomes (PROs) included in approved labeling of products in Europe and the USA. Two years after its launch, the coverage of FDA labels has been extended to give a more comprehensive image of the current use of PROs in clinical studies. **METHODS:** In 2006, the database opened with drugs approved in Europe through the centralized procedure established by the EMEA in January 1995 and with New Molecular Entities (NME) approved in the USA since January 1998. The extension project focused on other chemical types approved by FDA (e.g. New dosage form, New combination, etc.) and on NME approved before 1998. Once a PRO claim was identified in a label, the drug was added in PROlabels and the following information was retrieved: the PRO claim, description of clinical studies supporting the claim, description of PRO endpoints and measures used, pharmacological action of products and information source. **RESULTS:** Updated figures resulting from this major extension of PROlabels will be presented. These new figures will include the number of drug products present in the database with the FDA/EMEA distribution, the most represented therapeutic areas (currently nervous system diseases: 27.8%, immune system diseases: 20.6%, respiratory tract diseases: 16.5%, pathological conditions, signs and symptoms: 14.9%, and mental disorders: 14.6%), and the most frequently measured PROs (currently Signs and Symptoms followed by Health-Related Quality of Life (HRQL)). Finally, any change in the rate of PRO data found overall in FDA approvals will be checked. **CONCLUSIONS:** This extension of the FDA coverage of the PROlabels database allows a clearer picture of the use of PROs to assess patients’ treatment benefit to be drawn. In addition, it facilitates the examination of the discrepancies between the US and European regulatory agencies.

**PM C49**

**COMPARISON OF HEALTH LOCUS OF CONTROL BETWEEN PHYSICIANS AND THE GENERAL PUBLIC: MULTI-GROUP STRUCTURAL EQUATION MODELING**

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**OBJECTIVES:** Health locus of control (HLC) is associated with health-related behaviors such as adherence and participation in health screening. However, HLC among physicians may be different from that among the general public. It is important to understand the potential gap in HLC between physicians and the general public. The aim of the study included two steps: 1) to evaluate item bias of the HLC scale between physicians and the general public, and 2) to characterize HLC among physicians compared to the general public. **METHODS:** Data for the general public were obtained from the health diary study that involved a random sample from a nationally representative group of households in Japan. Physicians’ data were collected from a web-based survey of Japanese physicians. Multi-group structural equation modeling was used for examining item bias in the Japanese version of the HLC scale (HLCs-J) between the two groups. Differential item functioning (DIF), including uniform and non-uniform types, were used for measuring item bias. Dimensions with no uniform and non-uniform DIFs were then compared using multiple linear regressions. **RESULTS:** Data on the HLCs-J of 2194 people from the general public and 895 physicians were available. Uniform DIF was recognized for the dimensions of internal, professional control and control by spiritual powers. Chance and family control dimensions had no DIF. Mean score for chance control (17.2) among physicians was greater than that (14.9) among the general public (adjusted p < 0.001), while mean score for family control (21.7) among physicians was lower than that (22.1) among the general public (adjusted p < 0.001). **CONCLUSIONS:** Our psychometric evaluation of the HLCs-J indicates item bias in the dimensions of internal, professional control and control by spiritual powers. Physicians believe that chance has a greater impact but family control has a lesser impact on health than do members of the general public.

**PM C50**

**THE SUITABILITY OF VISUAL ANALOGUE SCALES (VAS) FOR COLLECTING PATIENT-REPORTED OUTCOMES (PRO) DATA FROM INTERNATIONAL SETTINGS**

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**OBJECTIVES:** The VAS is a common response scale in PRO questionnaires, which are used in multinational studies from which data is pooled. This study was designed to evaluate the suitability of VAS for use in different international settings, specifically to evaluate the cognitive processes and challenges occurring when respondents from a range of countries/cultures complete VAS. **METHODS:** Adults were recruited from: UK; Mexico; Spain; Malaysia; India; South Africa, with approximately 50:50 males/females and higher/lower education split. Each completed four VAS followed by a cognitive debriefing interview, once before and once after receiving standardized instructions. **RESULTS:** Thirty-seven lay persons were interviewed across 6 countries, mean age was 46 ± 19; 51.4% were male. Several respondents commented on the unfamiliar style of the VAS. Some reported the anchors as inappropriate/ambiguous, impeding scale completion, or that anchor wording caused them to avoid scale extremities. Respondents noted the lack of intermediate markers on the VAS, therefore having to rely on ‘guesswork’: most used quantitative rather than qualitative strategies when deciding where to place their mark. Some had concerns that ‘guesswork’ led to inaccurate responses. British and Spanish respondents used principally quantitative methods whereas Zulu speakers relied more on qualitative techniques. Respondents from Malaysia, South Africa and India were more inclined to complete VAS; Zulu and Tamil speakers completed the VAS in the least conventional way. **CONCLUSIONS:** The study provides substantial evidence that the use of VAS in different international settings
settings will result in data which has been influenced by differences in interpretation of the scale, providing support for the FDA’s perspective that VAS can provide a ‘false sense of precision’. This has implications for international clinical trials in which data pooling is required. This study allowed for a critical appraisal of the VAS response format which will assist in the collection of more valid data in multinational studies.

**PMCS1**

**UTILITIES OF THE EQ-5D: TRANSFERABLE OR NOT? INFLUENCE OF THE NATIONAL VALUE SETS OF THE EQ-5D ON THE INCREDULITY OF TWO HEALTH STATES**

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**OBJECTIVE:** In contrast to effectiveness of health care interventions, health states preferences might not be transferable between countries. A frequently used instrument to measure health-related quality of life is the EQ-5D, which has been developed to compare preferences across countries. Although the impact of using any of the fifteen national EQ-5D value sets on utility estimates is known, the impact on the incremental utility is unknown so far. **METHODS:** First, the relative influence of the EQ-5D domains on the utility estimate was assessed for each of the fifteen currently existing value sets. Second, two health states (21232 and 33321) were selected for further analyses. With the help of the two hypothetical health states we determined the influence of one or two point deteriorations of the health states. Based on this, the fifteen value sets were used to calculate incremental utility scores. **RESULTS:** Differences can be perceived between the value sets and between the valuation methods in the preferences for the domains of the EQ-5D. The utility scores of health states show that the differences between the value sets are substantial. Next to that, the dissimilarities between the increments of the deteriorations of the health states are large, independent of which valuation method is used. **CONCLUSION:** All results indicate that the differences between the value sets are considerable and should not be ignored. The magnitudes of the coefficients of the domains vary in a great extent, which causes dissimilarities when calculating the incremental utilities. As a consequence it can be concluded that the utility scores are not transferable across countries.

**CONCEPTUAL PAPERS & RESEARCH ON METHODS—Study Design**

**PMCS2**

**LINGUISTIC VALIDATION OF THE FRENCH FOR CANADA WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT QUESTIONNAIRE, GENERAL HEALTH VERSION (WPAI:GH)**

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**OBJECTIVES:** No measures of health-related absenteeism and presenteeism have been validated for use in French-speaking Canada. It is important to understand how illness affects an employee’s productivity and therefore an organization’s profitability; when ill, an employee may take a sick day (absenteeism) or attend work despite the illness and experience a loss of work efficiency (presenteeism). The WPAI:GH, a leading measure of work productivity and activity impairment questionnaire, General Health Version (WPAI:GH). **METHODS:** A Canadian French translation of the US English WPAI:GH was created through a reiterative process of creating harmonized forward and back translations by independent translators. French-speaking subjects residing in Canada self-administered the WPAI:GH and were subsequently debriefed by a bilingual (French-English) interviewer. **RESULTS:** Thirty French-Canadian subjects were interviewed, all of whom were currently employed at the time of the interview. The group was stratified by educational level, including an equal number of participants both with and without a high school degree. The WPAI:GH item comprehension rate was 97.2%; no response revisions were offered by any of the subjects. Responses to hypothetical scenarios indicated that the French for Canada language version adequately differentiates sick time taken for health and non-health reasons and between absenteeism and presenteeism. **CONCLUSIONS:** Linguistic validity of the French for Canada translation of the WPAI:GH was established among a diverse French Canadian population, including those with minimal education.

**PMCS3**

**IS UTILITY A LINEAR FUNCTION OF LIFETIME?**

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**OBJECTIVES:** In economic evaluation it is often assumed that utility is a linear function of lifetime. The aim of this study was first to test the assumption of linearity, for short increases in longevity, and second to test whether there exists a minimum threshold below which life extensions are not utility bearing. **METHODS:** A representative sample of the population (n = 2,400) was asked to imagine that they had a limited remaining lifetime (1 year or 10 years) and were offered a treatment that would increase lifetime by 1, 2, 4, 8, 16, 32 weeks (1 year perspective) or 2, 3, 8, 12, 32 or 52 weeks (10 years perspective). In each perspective, the price of treatment was constant per week life extension (i.e. constant proportions of acceptance across formats would indicate a linear utility function). Additionally, respondents were asked about their maximum willingness-to-pay (WTP) for the life extension. **RESULTS:** The proportions that accepted the treatment offer to the given price increased with increasing extensions (1 year: 48%, 54%, 55%, 59%, 59%, 61%; 10 years: 55%, 60%, 62%, 66%, 65%, 76%) indicating a convex utility function. In maximum WTP, the groups of respondents with increasing and diminishing marginal utility functions were of similar sizes. The proportions with zero WTP for the treatment declined from 34% for one week life extension to 14% for 52 weeks. The results were confirmed in various econometric models. **CONCLUSIONS:** While most health care programmes offer life extensions of less than one year, considerable proportions of the population may be unwilling to pay anything for such gains. For life extensions up to one year, most of the results indicate an increasing marginal utility function for lifetime.

**THE RIGOUR, FLEXIBILITY AND EASE OF IMPLEMENTATION OF SYSTEMATIC SEARCH STRATEGIES—DO WE NEED AN INDUSTRY STANDARD METHODOLOGY?**

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**OBJECTIVES:** Systematic reviews have become increasingly important in recent years, particularly to inform the inclusion of