demonstrated by studies of the burden to iron-overloaded patients receiving infused-ICT. Administration of infused-ICT was time-consuming, inconvenient, negatively impacted patients’ HRQoL, and up to 50% of UK patients had suboptimal treatment adherence, compromising morbidity and mortality. PROs in phase II/III clinical trials comparing the efficacy and safety of deferasirox with infused-ICT revealed that at each timepoint significantly more patients were ‘satisfied or very satisfied’ with deferasirox or found it to be ‘convenient or very convenient’ compared to previously received infused-ICT. Fewer hours were lost from daily activities, 77% preferred deferasirox, and more patients were willing to continue taking deferasirox than infused-ICT (84% vs. 11%). The French Transparency Commission acknowledged moderate improvement in medical benefit for deferasirox versus infused ICT considering improved HRQoL and adherence to ICT. Use of deferasirox is recommended.

CONCLUSIONS: PROs can increase key stakeholders’ awareness addressing concerns such as the medical importance of disease and unmet needs, the therapeutic value of products, and the benefits over existing treatments from the patient perspective.

WHAT PROPORTION OF DISEASES ARE QALYS AN IRRELEVANT MEASURE FOR?

Proudfoot CW, Alnwick K
Heron Evidence Development Ltd, Letchworth Garden City, UK

OBJECTIVES: Quality-adjusted life-years (QALYs) measure the number of years of perfect health provided by a health care intervention, and are a useful measure because they combine mortality and morbidity in one scale. QALYs are considered the “gold-standard” for assessing the effectiveness, and thus cost-effectiveness, of new interventions and are requested by most reimbursement agencies, such as the UK NICE. Utility data (generally gained through quality-of-life instruments) are required to calculate QALYs, however such data may not be available for some drug indications. As a result, these drug indications are not suitable for assessment via QALYs. We sought to clarify the extent to which this is a problem. METHODS: We reviewed all prescription drugs (including new preparations of existing drugs) approved by the UK regulatory agency, the MHRA. Using an online database of utility scores from Tufts University, we conducted various descriptive analyses. Our primary analysis was to establish the percentage of licensed drugs for which utility scores are available and thus for which QALYs are a possible effectiveness measure. RESULTS: Interim analysis of 93 licensed preparations showed that 73% had utility data available. This leaves a substantial proportion of drugs for which QALYs may be difficult or impossible to obtain. Where QALYs are difficult to obtain, this may limit the confidence with which they can be interpreted. In other cases, QALYs may be irrelevant: these include important indications such as anaesthesia and contraception. CONCLUSIONS: It is important for reimbursement agencies to recognise that QALYs are not a universal measure, and that flexibility is required for indications in which QALYs cannot be used. An over-emphasis on QALYs may lead to a bias against positive recommendations in disease areas where QALYs cannot be used.

A STUDY OF THE KEY FACTORS INFLUENCING THE PATIENT SATISFACTION IN INPATIENT AND OUTPATIENT SETTINGS

Tsai SF, Yeh GC
Taipei Medical University Hospital, Taipei, Taiwan

OBJECTIVES: This study was conducted in April 2007 at the Taipei Medical University Hospital, which is a district teaching hospital in Taiwan. The purpose of this study is to identify the most important determinants of the Patient satisfaction in the inpatient and outpatient settings. METHODS: Patient satisfaction was measured in a self written survey of inpatient and outpatient setting with the structured questionnaire including demography, environment, service manner, administration efficiency, process of diagnosis and treatment. This study collected data of 201 outpatient and 186 inpatient and were analysed with SPSS package. Stepwise regression analysis were conducted to help identify which factors were the most important in determining and chosen to make the best predicting model for patient satisfaction. RESULTS: Patients were generally satisfied with the mean score 4.12 and 3.77 in inpatient and outpatient respectively (scale 1 to 5, 5 being most satisfied). Through the stepwise regression analysis, in inpatient setting, the best fit for patient satisfaction standardized predicting model is: Patient Satisfaction(Y) = 0.997 disease relieved (R^2 = 0.954, F = 352.23, P < 0.001); In outpatient setting, the best fit for patient satisfaction standardized predicting model is: Patient Satisfaction(Y) = 0.235 hear patient reporting their condition with patient +0.249 manner of examination services +0.194 symptoms relieved +0.179 the air and the light of the hospital +0.169 waiting time for the diagnosis test result (R^2 = 0.666, F = 33.90, P < 0.001). CONCLUSIONS: The results reveal that the patient satisfaction standardized predicting model is: Patient Satisfaction(Y) = 0.997 disease relieved (R^2 = 0.954, F = 352.23, P < 0.001); In outpatient setting, the best fit for patient satisfaction standardized predicting model is: Patient Satisfaction(Y) = 0.235 hear patient reporting their condition with patient +0.249 manner of examination services +0.194 symptoms relieved +0.179 the air and the light of the hospital +0.169 waiting time for the diagnosis test result (R^2 = 0.666, F = 33.90, P < 0.001).
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 patient satisfaction.

**OBJECTIVES:** Health locus of control (HLC) is associated with patient satisfaction. The aim of the study included two steps: 1) 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. Dimensional 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.

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

**Caron M1, Emery MP1, Marquis P2, Pault E3**

1 Mapi Research Trust, Lyon, France, 2 Mapi Values, Boston, MA, USA

**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 symptoms and signs 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.

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

**Tokuda Y1, Ohde S2, Takahashi O1, Omata F1, Jacobs J1, Hinohara S2, Fukui T3**

1 St. Luke’s Life Science Institute, Chuo City, Tokyo, Japan, 2 St. Luke’s Life Science Institute, Chuo, Tokyo, Japan, 3 St. Luke’s International Hospital, Chuo, Tokyo, Japan

**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. Dimensional 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.

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

**Houchin C1, Nixon A1, Herdman M2, Juárez DM3, Labuschagne LA4, Manuel C5, Manuel F5, Wan Mahmud WMR6**

1 Oxford Outsourcing Ltd, Oxford, Oxon, UK, 2 Insight Consulting & Research, Madrid, Spain, 3 Independent consultant, Mexico City, Mexico, 4 Leona Labuschagne & Associates, Port Elizabeth, South Africa, 5 Independent consultant, Chennai, India, 6 Kedah Medical Centre, Kedah, Malaysia

**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 work: 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 use ‘guesswork’. Nevertheless, data from different international