Comparing the quality of life associated with various states of health: An international study

**OBJECTIVES**: This study assessed the quality of life associated with various states of health using the EQ-5D-5L, a widely used instrument to assess health state utilities. The EQ-5D-5L allows for the measurement of health outcomes across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each with five levels representing varying degrees of health status.

**Methods**: A cross-sectional survey was conducted among a representative sample of 2,000 adults in Germany, the United Kingdom, and the United States. The survey included questions about demographic information and health status.

**Results**: The study found that individuals in Germany reported a higher quality of life compared to those in the United Kingdom and the United States. Gender differences were also observed, with men reporting better health outcomes than women. However, the study noted that the results are consistent across most ages, with an increase in utility existing for adults aged 75 and older.

**Conclusions**: The EQ-5D-5L is a valuable tool for assessing the quality of life across different populations, and its use in international studies provides valuable insights into the health status of individuals worldwide.
cific terms, such as “discouraged” and “angered,” translate with greater conceptual equivalency. Therefore, when seeking to measure the various concepts associated with the term “frustrated,” measuring more specific constructs independently using separate questionnaire items is recommended.

PH74 REGULATORY ISSUES IN PRO ADVERTISING: A REVIEW OF THE DDMAC/OPDF LETTERS FROM 1998 TO 2013 TO IDENTIFY PRO CLAIMS VIOLATIONS AND EXAMINE THEIR EVOLUTION OVER TIME

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OBJECTIVES: According to the Federal, Food, Drug and Cosmetic Act (FD&C Act), prescription drug promotion must not be false or misleading, have fair balance, be balanced and accurately communicated. This study examined whether the Federal Trade Commission’s (FTC) Division of Drug Promotion (OPDF), formerly the Division of Drug Marketing, Advertising and Communications (DDMAC), was set up to protect the public health by ensuring prescription drug promotion is true, balanced and accurately communicated. The objective of this study was to review the DDMAC/OPDF warning and notice of violations letters to find out 1) how many violations were in relation to PRO and HRQoL claims and 2) how those evolved after the publication of the FDA PRO draft guidance in 2006. METHODS: DDMAC letters were identified on the “Enforcement Activities by FDA” webpage. Letters from 1998 to 2013 were collected and reviewed. RESULTS: A total of 331 PRO and HRQoL claims violations were identified. PRO and HRQoL claims violations were more frequent after the publication of the PRO draft guidance in 2006. In the pre-2006 period, PRO violations were more frequent than pre-2006 HRQoL violations. However, a reverse trend was observed in the post-2006 period, with more frequent HRQoL violations than pre-2006 PRO violations. CONCLUSIONS: Despite the publication of the PRO draft guidance in 2006, violations of PRO and HRQoL claims remain frequent and significant. More efforts are needed to improve the quality of PRO and HRQoL claims in drug promotion.

PH75 THE USE OF PATIENT REPORTED OUTCOMES (PROs) IN THE PHARMACEUTICAL INDUSTRY IN JAPAN – A BRIEF REVIEW OF PMID DATA IN COMPARISON WITH FDA AND EMA-APPROVED LABEL CLAIMS

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OBJECTIVES: The use of patient-reported outcomes (PROs) in label claims in the US, Europe, and Japan is regulated by the FDA, EMA, respectively. Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) does not have such regulations. This study was done to determine whether Japan-based pharmaceutical companies utilize PRO endpoints at all and in what way, by investigating their inclusion in FDA, EMA, or PMDA-approved clinical trials and drug information materials. METHODS: We searched the websites of ClinicalTrials.gov and the PMDA for information on 14 drugs which had received PRO claim approvals from both the US and Europe or Japan up until 2010. Search terms were the generic and/or brand names of the selected drugs (in English and Japanese, as appropriate). PROs were classified as “symptoms”, “functioning”, and “HRQOL” based on the PRO scale used. A table comparing PRO type, endpoint positioning, and US and Europe-approved label claims was provided. RESULTS: A table of PRO information was created. RESULTS: Of the above fourteen drugs, four are not yet available in Japan. One drug with an FDA and EMA-approved “symptoms” claim did not have such in its Japanese clinical trials. While nine remaining drugs, the PRO endpoints followed: two drugs, indicated for epileptic seizure and for benign prostatic hyperplasia, had “symptoms” as a primary endpoint; a drug for rheumatoid arthritis (RA) had “disability” as its lead secondary endpoint; the remaining six drugs (for pulmonary arterial hypertension (PAH), Crohn’s Disease, smoking cessation, Myasthenia Gravis, asthma, and overactive bladder) had “HRQOL”, “symptoms”, and “functioning” as secondary minor endpoints. Three drugs -indicated for PAH, seizure, and RA- had PRO claims on their labels. Although not yet available in Japan, PROs are used in drug clinical trials and label claims. Symptoms, Quality of Life, and Functioning are the most common PROs used.

PH76 COMPARING THE EQUIVALENCE OF EQ-SD-SL ACROSS DIFFERENT MODES OF ADMINISTRATION

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OBJECTIVES: Interest in delivering Patient Reported Outcome Measures (PROMs) using mobile phones has increased in recent years. However there is debate about the level of equivalence between the traditional pencil and paper and electronic modes of administration. The aim of this study is to compare the equivalence of delivering a widely used generic PROM (EQ-SD-SL) pencil and paper and mobile phone administrations. METHODS: A mobile version of the EQ-SD-SL was developed with guidance from the EuroQol Group. Two hundred respondents from a research cohort of people in South Yorkshire were identified, and randomly allocated to one of the administration modes based on stratifications for age and gender (and across a range of self-reported health issues). The EQ-SD-SL was completed either using a mobile device or the standard paper version which was sent to out the respondent. Follow up usability questions were also included. EQ-SD-SL equivalence was compared at the dimension and utility and VAS score level using ANOVA. RESULTS: Response rates were comparable across the arms, with the majority of respondents owning a smartphone. The mean EQ-SD-SL utility and VAS score of respondents endorsing the individual EQ-SD-SL categories across each of the dimensions does not differ across the administration modes. The majority of the mobile phone completion sample agreed that the mobile version was completed, and that the journey was easy. CONCLUSIONS: Completing e-PROMs using mobile phones produces equivalent results and response rates to pencil and paper methods, and respondents are positive towards completing questionnaires using these methods. This study provides evidence that e-PROMs are valid for use to collect data in a range of settings including clinical trials, routine care, and, as for example, health diaries.

PH77 ARE PATIENT REPORTED OUTCOMES RELEVANT TO PATIENTS? LEARNINGS FROM A PATIENT ADVOCATE SURVEY

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OBJECTIVES: Increasingly, patients become active participants in making decisions on their therapy. A survey was conducted to understand the experience and expectations of patient organizations (POs) with patient reported outcomes (PRO) as they are measured today. METHODS: An online survey was conducted in English language in May 2014 among members of a patient organization (PO) and a patient forum to prepare a discussion of the relevance and usefulness of patient reported outcomes from the patient perspective. The participants represented a broad range of disease-specific and disease-independent patient organizations from various countries including USA, European countries, Asia, Latin America, Middle East and Australia. RESULTS: Current PROs were perceived as useful but not optimal for informing patients in making their own therapy decisions. All typical PRO domains were considered important (between 3.9 and 4.7 on a 5-point scale) with the most important being symptoms (4.6±0.89), Physical Function (4.6±0.59) and psychological well-being (4.7±0.47). The participants thought that PROs should be part of all studies throughout the entire life cycle of products including evidence for clinical research, reimbursement decisions, listing decisions, health technology assessment (HTA) or comparative effectiveness (CEB) studies (all between 4.2 and 4.6 on a 5-point scale). Increasingly, POs develop their own instruments to elicit PROs from the patient perspective and as patient based evidence. CONCLUSIONS: The concept of patient reported outcomes is good in principle but more is needed for integrating additional aspects which are relevant for the patients themselves to understand the full impact and consequences of the therapy. Patient reported outcomes are a key endpoint from the patient perspective and should be elicited throughout the entire development and marketing cycle of products.