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.

PIH73
MOBILE PHONE USE IN PATIENT REPORTED OUTCOMES– AN UPDATED LITERATURE SEARCH
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OBJECTIVES: To demonstrate the increasing use of mobile phones to collect patient reported outcomes in research as a valid method of data collection. **METHODS:** A literature search was conducted looking at articles published between 2009 and 2014 that referenced electronic diaries of some description. Articles were pulled out that specifically referenced mobile or cellular phones. **RESULTS:** 39 of out of 191 articles found specifically referenced mobile. The studies referenced were carried out on populations with an age range of 8 years up to 80 (mean 35.4; SD 16.6) and were split into 15 therapy areas including metabolic and genetic disorders, pain, weight management, sexual activity, respiratory, multiple sclerosis and gastroesophageal reflux disease. Population size ranged from 12 to 994 (mean 208.3; SD 269.2), and subjects reported for a minimum of 7 days (up to 6 reports per day) to a maximum of 2 years (mean 154.3 days; SD 170.6). Notably, 18 out of the 39 studies allowed the subjects to use their own mobile phone for the reporting and 19 articles referenced smartphones specifically. **CONCLUSIONS:** All concluded that mobile phones were suited to collect data from subjects. It was noted that the use of mobiles was acceptable as they are used them in everyday life and found to be convenient; the technology was also inexpensive to implement. The fact that 46.2% of the studies allowed the subjects to use their own mobile phones for the reporting emphasises the practicality of using mobile phones in patient reported outcomes. Although the mean age of all the studies was relatively low, the age range was very wide and researchers can be confident that older populations could use mobile phones to collect these data. The technical evolution of mobile technologies and ubiquitous nature show that this technology is a valid means to collect patient reported outcomes.

PIH74
REGULATORY ISSUES IN PRO ADVERTISING: A REVIEW OF THE DDMAC/OPDP 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 consistent with the approved product labeling, and only include claims substantiated by adequate and well-controlled clinical studies. The Office of Prescription Drug Promotion (OPDP), formerly the *Division of Drug Marketing, Advertising and Communications* (DDMAC), was set up to protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. The objective of this study was to review the DDMAC/OPDP warning and notice of violations letters to find out 1) how many violations were in relation to PRO and HRQL 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 all reviewed manually to identify violations in relation to PRO and HRQL claims during the periods before and after the publication of the guidance (1998-2005 vs. 2006-2013). **RESULTS:** 763 letters were reviewed. Each letter included information about one or more violations of the FD&C Act, such as "Omission of Risk Information", "Overstatement of Efficacy", "Unsubstantiated Superiority Claims", etc. The review showed a letter volume on the decline (n=524 for 1998-2005, n=239 for 2006-2013), with an increase in PRO violations: 19.50% of all letters (1998-2005) vs. 30.5% (2006-2013). HRQL violations were rarer after 2006 and were more often detected as implicit: 20 false HRQL claims, of which two were considered implicit (1998-2005) vs. seven false HRQL claims, of which four were considered implicit (2006-2013). Examples will be presented. **CONCLUSIONS:** The FDA guidance on PRO measure seems to have had an influence on HRQL information: less ads with explicit violations and a OPDP's tendency to argue over implicit claims.

PIH75
THE USE OF PATIENT REPORTED OUTCOMES (PROS) BY THE PHARMACEUTICAL INDUSTRY IN JAPAN – A BRIEF REVIEW OF PMDA 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 and Europe is regulated by the US FDA and the 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 of PROs in pharmaceutical 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 FDA and EMA from 2006-2010. 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 versus the PRO information reported in Japan for the same drug 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 Japan clinical trial. Of the nine remaining drugs, the PRO endpoints were as follows: two drugs, indicated for epileptic seizure and for benign prostatic hyperplasia, had "symptoms" as a primary endpoint; a drug for rheumatoid arthritis (RA) had "functioning" 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 minor secondary endpoints. Three drugs -indicated for PAH, seizure, and RA- had PRO claims in their labels. **CONCLUSIONS:** Although not yet prominent in Japan, PROs are used in drug clinical trials and label claims. Symptoms, Quality of Life, and Functioning are the most common PROs used.

PIH76
COMPARING THE EQUIVALENCE OF EQ-5D-5L ACROSS DIFFERENT MODES OF ADMINISTRATION
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OBJECTIVES: Interest in delivering Patient Reported Outcome Measures (PROMs) using mobile devices (e-PROMs) 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-5D-5L) pencil and paper and mobile phone administration modes. **METHODS:** A mobile version of the EQ-5D-5L 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-5D-5L was completed either using a mobile device or the standard paper version which were sent out to the respondent. Follow up usability questions were also included. EQ-5D 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-5D-5L utility and VAS scores and the frequency of respondents endorsing the individual EQ-5D-5L 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 of EQ-5D-5L was easy to complete, and that the phone was easy to use, and that they would complete e-PROMs again. **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 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.

PIH77
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 throughout May 2014 among 40 participants at a global cross disease 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, Latina 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 of 9 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 (4.65±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 (CER) studies (all between 4.25 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 endpoints from the patient perspective and should be elicited throughout the entire development and marketing cycle of products.

PIH78
THE ENDOMETRIOSIS HEALTH PROFILE (EHP) – A CASE STUDY OF SUCCESSFUL EPRO COLLABORATION
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OBJECTIVES: To migrate the UK English Endometriosis Health Profile (EHP) from paper to ePRO format for completion by respondents on a touchscreen tablet device. Following migration, to produce translations of the UK English ePRO version in 25 languages. **METHODS:** The draft ePRO version of the EHP was reviewed by the questionnaire developer, the translation project manager and the sponsor. During the initial review the questionnaire was assessed for linguistic equivalence with the paper version and for usability in relation to the target patient group. A number of factors were considered including layout, response input method and forced completion. Decisions were made based on the recommendations of the developer, translation vendor and ePRO vendor according to the specialism of each party, taking into consideration the capabilities of the software and the requirements of the

patient group. Following the initial review the tablet-based ePRO version was pilot tested with 10 endometriosis patients who were native speakers of UK English. The translated versions of the EHP were adapted for ePRO administration and the resulting screenshots proofread for accuracy. **RESULTS:** Feedback from patients indicated that some amendments to the formatting and ordering of instructions would be beneficial. However, all respondents indicated that the ePRO version of the EHP was easy to use and preferable to a paper-based questionnaire. The ePRO format posed some difficulties for specific languages which required an adjustment to the layout or wording structure. **CONCLUSIONS:** Cognitive debriefing and usability testing confirmed that the ePRO version of the questionnaire was an accurate representation of the original paper version. This was achieved via cooperative input at the initial review stage to ensure that all aspects were considered and close collaboration throughout the project to find appropriate solutions to the challenges posed by the ePRO administration of the EHP.

PIH79

EVALUATING THE TRANSLATABILITY OF PHYSICAL ASSESSMENT CLINICAL OUTCOMES ASSESSMENT (COA) ITEMS

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OBJECTIVES: The objective of this study is to determine which physical assessment Clinical Outcomes Assessment (COA) questionnaire items are most translatable. **METHODS:** Eighteen (18) physical assessment items were analyzed, using back-translations to determine conceptual equivalency with the source text. Previous studies have regarded 80% source conceptual equivalency as a translatability benchmark. Translator feedback regarding cultural appropriateness also influenced whether certain physical assessment items were optimal for use in questionnaires, as some items might be translatable, but not appropriate for the target country. **RESULTS:** Physical assessment items were grouped into three categories: highly translatable, moderately translatable, and problematic. Highly translatable examples, "running errands," "getting around town" and "washing yourself" were translated with conceptual equivalency 100% of the time, and were considered culturally appropriate for all languages. Moderately translatable items, such as "taking a trip" may be misconstrued, as the distance implied may differ across languages. "Bathe yourself" was translated with 87% conceptual equivalency, and may be misunderstood as "taking a bath," when the intention is to clean oneself. Problematic items, such as "going out," translated with conceptual equivalency only 76% of the time, requiring a destination or activity to be comprehensible in other languages. "Walking a block," although achieving 84% conceptual equivalency, is not applicable nor understood in many languages. When measuring distance walked, it is recommended to be specific, using examples such as 100 meters or a kilometer. **CONCLUSIONS:** Specific concepts appear to be more translatable and universal, such as "getting around town" and "walking 100 meters. " Items left open for interpretation, such as "bathing yourself" or "taking a trip" can cause moderate translation difficulties. Additionally, many languages cannot coherently translate less specific items, such as "going out," or translate culturally specific items. Although "walking a block" is translatable, such an example is unlikely to be understood in many languages.

PIH80

THEORETICAL AND PRACTICAL POSSIBILITIES OF THE MEASUREMENT OF POSTOPERATIVE PAIN IN OBSTETRIC INTENSIVE WARD

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OBJECTIVES: The measurement of the degree of pain and the exploration of influencing factors to compare data about the evaluation of postoperative pain given patients and nurses on a numeric scale. The connection between BMI index, age and verification of need for opiate associated with BMI was evaluated. Our aim was to measure whether nurses underestimate the level of pain in patients as well to show the advantages of multimodal analgesia and the additional opiate needs. **METHODS:** The survey was conducted between the 1st November and 15th of December in 2013 among 40 patients who had surgery and 10 nurses dealing with them afterwards. Data was collected at the sub intensive ward of the Department of Obstetrics and Gynaecology, University of Pécs. The analysis of results was performed with MO Excel 2007 program. For data analysis absolute and relative frequency, Chi-square test, two-sample t-test, correlation and linear regression analysis besides the significance level p<0,05. Results were presented with main confidence interval. **RESULTS:** Nurses underestimated the patients' pain value (p=0,011). Tight and continuous connection with the patient's vital parameters had not been proved (p>0,05). Connection was not found between the age and BMI index of the patients (p=0,134), however in case of the mostly overweight sample group the need for opiate wasn't increased (p=0,62). It is shown by the survey that open surgeries aren't result in higher pain value which was not significant after adequate analgesia (p>0,05). The benefit of multimodal therapy in analgesia had been proved, although it had not resulted in decreased need for opiate (p=0,807). **CONCLUSIONS:** It is essential to conduct a survey on the knowledge of health care workers in the future and to organize possible workshops and create protocols. Moreover, pain should be monitored minimum three times a day (Shugarman LR., 2010, Canada).

PIH81

HEALTH RELATED QUALITY OF LIFE IN PATIENTS RECEIVING HOME ENTERAL NUTRITION IN SPAIN ASSESSED BY A SPECIFIC QUESTIONNAIRE: NUTRIQOL®

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OBJECTIVES: To assess Health Related Quality of Life (HRQoL) in patients receiving Home Enteral Nutrition (HEN) using NutriQoL® questionnaire in Spain. **METHODS:** NutriQoL®, a specific questionnaire, developed and validated in Spain, for the assessment of HRQoL of patients receiving HEN regardless of the underlying condition was administered to a prospective cohort from 9 Spanish hospitals. It includes 17 pairs of items of HEN-related HRQoL grouped in two dimensions: 1) physical functioning and activities of daily living; 2) social life aspects, scoring from -51 (worst HRQoL) to 51 (best HRQoL). Cluster analysis using k-means identified groups of patients with similar HRQoL. **RESULTS:** A total of 140 subjects (61.4% men; mean (SD) age: 62.7 (15.41) participated. NutriQoL® mean total score was 14.98 (14.86). Dimension 1 and 2 scored 13.55 (11.71) and 1.40 (4.74). Cancer patients presented lower HRQoL compared to neurological and malabsorption patients (12.76 vs. 18.11 vs. 17.37; p=0.098). Patients receiving oral HEN as a supplement referred higher HRQoL than those receiving HEN by gastrostomy or nasogastric tube (19.54 vs. 14.00 vs. 7.02; p<0.001) as their only nutrition route (19.33 vs. 8.18; p<0.001). Up to 71.4% of patients referred HRQoL improvements since the introduction of HEN. Cluster analysis resulted in 4 groups according to NutriQoL® score. Cluster 1 [32.23 (5.83)]: Neurologic patients receiving oral HEN as a supplement. Cluster 2 [18.19 (3.94)]: oncologic disease receiving HEN by gastrostomy as a supplement. Cluster 3 and 4: [3.9 (4.67) and 12.21 (5.95)]: oncologic patients receiving oral HEN as a supplement, with differences in terms of severity (Charlson index 2.45 (2.65) vs. 3.14 (2.57). **CONCLUSIONS:** NutriQoL® results demonstrated a sample with a fairly good HRQoL, where the introduction of HEN had improved their HRQoL. In patients receiving HEN, physical functioning and activities of daily living were better predictors than social life domain.

PIH82

QUALITY OF LIFE IN PREGNANT WOMEN ATTENDING ANTI-NATAL CLINICS IN RURAL AND URBAN AREAS OF DELTA STATE

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OBJECTIVES: Preventing problems for mothers and babies depends on an operational continuum of care with accessible, high quality care before and during pregnancy, childbirth, and the postnatal period. The objective of this study is to evaluate the quality of life of pregnant women attending antenatal clinics in rural and urban areas of Delta State, Nigeria. **METHODS:** A descriptive cross sectional study design was used. Six hundred and ninety nine pregnant women attending antenatal clinics in selected hospitals were interviewed using a 31 item pretested, structured questionnaire developed using the World Health Organization Quality of Life (WHOQOL) on Pregnancy assessment brief template. Data assessed include socio-demographics and questions relating to physical, psychological, social and environmental health were used to assess the health related quality of life values in each of the study participants. Data collected were analyzed using the Statistical Package for Social Sciences (SPSS) software version 16.0. The level of statistical significance was set at P<0.0001. **RESULTS:** The mean age of the respondent was 27±5.04. The HRQOL mean scores were highest for the environmental domain (26.39±5.34) and lowest for the social relationship domain (11.43±1.81). The overall QOL mean scores in the other two domains were: physical health (24.84±3.74), psychological health (21.84±3.03). Significant differences were observed in all domains except social relationship. **CONCLUSIONS:** The health related of life (HRQOL) in pregnant women was found to be lower in those living in the rural areas than their counterparts in the urban areas in all domains except social relationships.

INDIVIDUAL'S HEALTH – Health Care Use & Policy Studies

PIH83

HOSPITAL DRG COSTING AND HEALTH SERVICES USE OF VERY PRE-TERM INFANTS FROM THE PROPREMS NEURO STUDY ACROSS 10 HOSPITALS IN AUSTRALIA AND NEW ZEALAND

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OBJECTIVES: Mortality and morbidity of very preterm (born <32 weeks' gestation) and very-low-birth-weight (VLBW, <1500g) infants impose substantially on finite health resources. This study estimated costs of hospital and non-hospital services for a cohort enrolled in ProPrems Neuro, of very preterm/VLBW infants from birth to 24 months' age corrected for prematurity. We also tested the sensitivity of results to the costing approach used. **METHODS:** ProPrems Neuro study assesses the 2-year outcomes of very preterm/VLBW infants from Australia and New Zealand from 2007-2011 in a prospective multicentre, double-blinded randomised controlled trial of probiotic administration. Infants' health resource use was collected from medical assessment records at birth hospitals, parent report and, with parental consent, from Medicare Australia (Government database) for resource use up to 24 months. Hospital costs were calculated separately by the Victorian (State) Casemix funding approach and the newly implemented national activity-based funding (ABF) algorithm. AR-DRG diagnostic/procedural codes were used to classify inpatient episodes by prematurity/birth weight, complications, length of stay (LoS), hospital and patient characteristics. Costs were measured in 2013 Australian dollars. **RESULTS:** 1099 preterm infants across 10 hospitals were included. Average costs were highest for infants with birth weight <750g: $224,158 with mean LoS 105 days. Cost comparison between Casemix and ABF systems showed significantly lower costs using the national algorithm. Mean cost difference for the largest participating hospital was $9132 (95%CI 5998, 12267; p<0.001). Final results of infant health service use to 2