Indonesia Demographic and Health Survey data of 2007 was obtained from Measured DHS using a randomized subset of 1,470 observations. Multinomial and binomial logistic regression were performed to assess assocations between long-term, short-term and no contraception with wife's age, wife's education, husband's education, number of children ever born, wife's religion, wife's working status, husband's occupation, and wealth index. **RESULTS:** Wife's education, wealth index, number of children ever born, and wife's age were statistically significant at the 95% CL. Overall, accounting for all categorical levels of wife's education and wealth index both were statistically significant while the difference between each category were not statistically significant. The wife's education at a secondary level (OR: 2.05; 95% CL, 1.26-3.35) was the most likely to choose any contraception (short or long term) while the wife with a wealth index (OR: 1.73; 95% CL, 1.24-2.42) at the third quintile was the most likely to choose any contraception (short or long term). Within contraception categories (short or long term), the wife with a higher education or in the top quintile of the wealth index was the most likely to choose short-term contraception. For long-term contraception, the wife with a secondary education and in the third quintile of wealth were more likely to choose that method. **CONCLUSIONS:** Wife's education and wealth index indicate contraceptive choice. Between short-term and long-term contraceptive choice, wife's education and wealth index increases are indicative for short-term but not for long-term warranting analysis of other socio-economic factors in association.

PIH62

A REVIEW OF FDA WARNING LETTERS AND NOTICES OF VIOLATION ISSUED FOR PATIENT REPORTED OUTCOMES PROMOTIONAL CLAIMS BETWEEN 2006-2012

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OBJECTIVES: To ascertain the frequency and types of PRO violations made in US pharmaceutical promotional materials between 2006 and 2012 and determine if there were increases in violation warnings following issuance of the FDA draft and final PRO guidance. **METHODS:** Warning letters or notices of violation issued by the FDA's Office of Prescription Drug Promotion (OPDP) were reviewed for PRO violations (n=213). Type of violation was classified as: (1) PRO not fit for purpose; (2) Study design/Interpretation of results; (3) Statistical analysis; and/or (4) No Treatment benefit. **RESULTS:** Of the 213 letters reviewed, 19% contained a PRO violation (n=41); 15 (37%) were warning letters and 26 (63%) were notice of violation letters. The most common violation was PRO not fit for purpose (54%) e.g. use of individual items (45%), content validity (36%), and broadening of the claim beyond what the PRO measures (27%). Issues with Study design/Interpretation of results were also high (49%), particularly broadening of claim beyond what was measured in the trial (55%), and no PRO used (50%). Fewer WLs/NOVs specified statistical issues (24%) but, most were because of lack of pre-specification of the analyses conducted (50%). Over half of the violations fell into more than one category (54%). PRO violations were issued across a wide array of therapeutic areas; pain drugs had the highest frequency (24%). Violations primarily occurred in professional sales and detail aids (22%), brochures (14%) and videos (11%). **CONCLUSIONS:** A fifth of letters issued to companies contained PRO violations with most of this related to poor selection of the PRO measure used or trying to broaden the claim. More guidance from OPDP about what is considered 'substantial evidence' in this area could help reduce the number of letters issued.

PIH63

GENDER DIFFERENCES IN COGNITIVE DEBRIEFING OF TRANSLATED PATIENT QUESTIONNAIRES

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OBJECTIVES: The objective of this study was to determine if any discernible differences, in quantity or content, exist in feedback from male and female subjects during cognitive debriefing interviews of translated patient questionnaires. **METHODS:** Cognitive debriefing took place with subjects diagnosed with Ulcerative Colitis, Stroke, COPD and Diabetes, across 54 different languages. Comments were classified as either those resulting in a translation revision made to improve comprehensibility, cultural appropriateness or grammar, or those leading to no revision, due to a stylistic suggestion or a source text deviation. The average number of comments made per subject was calculated for each classification, as well as a p value for the total using a two tailed t test. **RESULTS:** Out of the total sample (n=351), 171 respondents were male and 180 were female. The average number of comments made was 3.05 per male subject and 4.22 per female subject, with a p value of 0.006. For comments that resulted in a translation revision, per questionnaire, males averaged 0.95 comments and females averaged 1.19 comments, with a p value of 0.16. For comments that resulted in no revision, per questionnaire, males averaged 1.62 comments and females averaged 2.44 comments, with a p value of 0.02. **CONCLUSIONS:** The results show that females, overall, make more comments during cognitive debriefing interviews than men. Additionally, females tend to make more comments that do not result in a translation revision, which may be stylistic or source deviation comments. For comments that result in a translation revision, there is no meaningful difference between males and females as demonstrated by the marginal difference between the two means and the p value. Both males and females contribute equally to ensuring a final translation is culturally appropriate and comprehensible.

PIH64

IDENTIFYING TRENDS AND IMPACTS OF THE FDA GUIDANCE FOR INDUSTRY ON PATIENT-REPORTED OUTCOMES (PROS) ON APPROVED PRODUCT LABELS, 2006–2013

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OBJECTIVES: From 2006 – 2013 the FDA approved 207 new molecular entities (NMEs), which included 84 efficacy statements supported by PRO assessments. In addition to NMEs, many previously-approved product labels were updated with PRO statements during this period. The purpose of this research was to review the efficacy claims supported by PROs to identify trends amongst the approved indications and differences between approved claims before and after finalization of the guidance. **METHODS:** NME labels approved by the FDA from 2006 – 2013 were reviewed on the Drugs@FDA website; updated labels were discovered via literature and Internet searches. An assessment or statement of efficacy was considered to be PRO-based if it assessed symptoms, side effects, or impacts on functioning and daily activities, entirely from the patient perspective. **RESULTS:** From 2006 – 2013, the FDA approved an average of 25.9 NMEs per year. The average number of PROs included in NME labels from 2006 – 2010 was 14.2 per year (n = 71). From 2011 – 2013, the average was 4.3 PROs approved per year (n = 13). The difference between these two periods is statistically significant ($t = 4.85$, $p = .002$). Further investigation revealed 22 non-NME labels with PROs newly approved during this period, with no notable per-year trends. **CONCLUSIONS:** The FDA's PRO Guidance may not be the lone cause for the reduction of approved PROs in NME labels, but there was a significant drop in the number of approvals following its finalization. While the number of PROs approved in 2010 was similar to the numbers approved 2006 – 2009, submissions reviewed in 2010 may not have been asked to meet the standards of the PRO Guidance, thus impacting our analysis. Inclusion of non-NME labels approved from 2006 – 2013 does not increase the percentage of PROs approved.

PIH65

RISK PERCEPTION OF MEDICATION SIDE EFFECTS: A PRODUCT OF SIDE EFFECT CHARACTERISTICS, STYLISTIC FACTORS OF THE COMMUNICATED MESSAGE OR BOTH?

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OBJECTIVES: To evaluate effect of side effect characteristics (frequency and severity) and stylistic factors (plain language or plain language combined with numeric frequency) on risk perception of side effects. **METHODS:** About 100 participants were randomly presented with four of eight conditions with information about medication side effects in a 2 (side effect frequency: low, high) X 2 (side effect severity: mild, severe) X 2 (communication style: plain language, plain language combined with numeric frequency) experimental design. The participants were then asked to rate their risk perception with each of the four conditions. Test for analysis of variance was performed. **RESULTS:** As compared to plain language only, the use of combination of plain language and numeric frequencies to communicate side effect information lead to an increase in risk perception for mild side effects of high frequency (difference between mean risk perception scores = 25.30, $p<0.001$). The mean risk perception scores did not differ significantly across the two communication styles for severe side effects of high frequency, severe side effects of low frequency and mild side effects of low frequency. With plain language communication style the difference between mean risk perception scores across two frequency levels was 42.68 ($p<0.001$) for mild side effects whereas that for severe side effects was 61.59 ($p<0.001$). Similar effects were seen with combination communication style (mild side effects: difference between means= 70.34, $p<0.001$; severe side effects: difference between means= 70.07, $p<0.001$). With communication style and frequency kept constant, change in severity did not have any effect on the risk perception scores. **CONCLUSIONS:** Frequency of side effects play a major role in evaluation of personal risk of side effects. Stylistic factors also affect risk perceptions to some extent based on the effects of frequency. These results may help health care providers in utilization of appropriate methods for communicating risk of medication side effects.

PIH66

DEVELOPMENT OF A MEDICATION-PROBLEM COPING SCALE (MPCS) AND ITEMS CALIBRATION USING ONE-PARAMETER LOGISTIC (1PL) AND TWO-PARAMETER LOGISTIC (2PL) MODELS

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OBJECTIVES: Adverse drug problems (ADPs) have caused significant morbidity and mortality to patients. The objective of this study was to develop a medication-problem coping scale (MPCS) to measure patients' coping responses to their ADP and calibrate the developed items using one-parameter logistic (1PL) and two-parameter logistic (2PL) models. **METHODS:** A comprehensive literature review was conducted to identify candidate items to measure patient's coping strategies when dealing with perceived ADPs. Supplementary items were then added to fill in the content gaps. The items were administered to patients in the community pharmacies which are incorporated into the Minnesota practice-based research network (PBRN). After collecting data from 140 patients, eleven items which met the assumptions of item response theory were calibrated using the 1PL and 2PL models respectively to determine which model is favored. **RESULTS:** The 1PL and 2PL model were compared by taking goodness-of-fit statistics, reliability of the estimated person scores, and standard error of measurement (SEM) into account. First, the chi-squared difference test was highly significant ($X^2(41.61, 10)$, $P<0.0001$) indicating that the 2PL model provided a better fit to the item responses compared to the 1PL model. This result was supported by the information-theoretic fit index (AIC) and the RMSEA value, all of which favored the 2PL model. In addition, the 2PL model was preferred with a higher value of score reliability estimate (0.82) compared to that of the 1PL model (0.79). Finally, the 2PL model had much more information and much lower SEM over most of the coping behavior range. **CONCLUSIONS:** Our findings indicated that the 2PL model was preferred than the 1PL model. It suggests that the 2PL model be used to obtain item parameters and to assess information function.