their uninsured status. The current study aimed to evaluate the effect of a new health system from the perspective of the insured students one year after program implementation. METHODS: Based on the Chinese Customer Satisfaction Index and review of the literatures, we built a satisfaction evaluation system for URMS of university students, with one first-level, 7 second-level (latent variable, x9) and 24 third-level indicators (Explicit variable, y8) to be scored on a five-point Likert-type scale. After a preliminary assessment of subsequent questionnaire, 400 questionnaires were handed to students in 4 universities in NE.China. After obtaining the affecting order of third indexes to their corresponding secondary index through the correlation test, a Structural Equation Model (SEM) for the satisfaction assessment of URSM was built basing on the calculated Path coefficient between the x9 and y8 after multiple regression. Goodness of fit statistics of SEM were compared with the original model, which has a slight difference between this model and satisfaction assessment. RESULTS: A total of 393 questionnaires were returned giving a recovered rate 98.3%. The path coefficients between x9 and y8 were: customer trust 1.26, the perceived quality 0.88, customer complaints 0.26, customer satisfaction 0.29. The satisfaction score of UMRS (29.06 out of 69.75 points) was determined by the composite of the first and second indexes to their corresponding secondary index through the correlation test, the government 0.29. The satisfaction score of UMRS (29.06 out of 69.75 points) showed very low satisfaction level of university students towards the program. CONCLUSIONS: The results showed the satisfaction assessment model was suitable for the study. Based on the order of path coefficients, several reform proposals for improving university students’ medical insurance are proposed, including establishing a multi-level medical insurance system with corresponding regulatory and monitoring mechanism of its performance; as well as enhancing awareness and education of students about health insurance.

**PIH46**

**THE STATE OF THE DRUG PROVISION SYSTEM OF KAZAKHSTANI POPULATION WITHIN THE SCOPE OF THE EXTENT OF THE FREE GUARANTEED MEDICAL ASSISTANCE**

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**OBJECTIVES:** To determine the level of availability and transparency of the drug provision system of Kazakhstani population at the expense of the governmental budget and to detect the level of their satisfaction. METHODS: A total of 1236 patients filled the random anonymous questionnaire in polyclinics and hospitals in Almaty, Astana, Kyzylorda and Karaganda regions. The questionnaire consisted of 38 questions. RESULTS: A total of 51.6% of the patients were provided with drugs by the reduced price with the substitution coefficient of 0.5. Almost 47% of the patients were refused to be provided with medical assistance and drugs within the scope of the extent of the free guaranteed medical assistance further, 80.3% of the asked had to use additional amounts of their own money during not only at the ambulatory but also at the hospital level. At the same time, it was unaffordable for 63.8% of the asked to buy drugs. A total of 57.9% of the patients defined the drug availability provided within the scope of the guaranteed free medical assistance as poor and unsatisfactory. Moreover, 76.8% claimed that several medicines were absent in the current and last year lists. In order to protect their rights, the patients applied to medical organizations (27.9 %), to local public health services (21.9 %), to social patients protecting services (11.1 %), to courts (4.3 %) and others (17.1 %). In 43.7% of cases doctors either had not explained their prescription or rarely -17.3. 42% were dissatisfied with their doctors; moreover, 71.5% of the patients suggested that educational brochures containing information on the disease, side effects of the prescribed medicines, etc. should be provided.

**CONCLUSIONS:** There are problems with the drug provision within the scope of the extent of the free guaranteed medical assistance which mainly concern with poor availibility of medicines and low compliance.

**PIH47**

**SYMPTOMS AND MANAGEMENT OF TEETHING: PARENTS REPORTED OUTCOMES**

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**OBJECTIVES:** Teething is a natural occurrence of childhood, yet there is no consensus regarding what symptoms are associated with teething and whether medical treatment relieves these symptoms. The objective of this study was to assess what symptoms parents ascribed to their child’s teething and how satisfied they were with the how their paediatrician managed the teething with existing medicines. METHODS: We conducted a prospective observational study where a randomly selected 500 French pedestrians were asked to fill out case reports of the first four 3 to 24 month old patients they treated for teething. Of these, 161 agreed to particpate and filled out case reports of medical and treatment data for 597 children at baseline. A total of 412 parents filled out a satisfaction questionnaire and a 7-day diary assessing teething symptoms and severity. RESULTS: The median age was 6 months, 58.5% were male and for 49.8% of them it was the first teething experience. At baseline, the average number of symptoms parents ascribed to teething was 5.1, with the main symptoms including gums tumefaction (80.5%), saliorrhoea (70.3%), and unusual agitation/irritability (67.1%). Seven days after a treatment was prescribed, the symptoms were displayed by the child, a decrease of 1.7 symptoms was observed, a decrease of 46.9%, and 31.7%, respectively. Overall, 85.7% of parents indicated that they give their child medication for teething, 80.7% of the parents were “satisfied” or “very satisfied” with the treatments prescribed and 83.2% were willing to use it for a future tooth eruption of their child. Satisfaction did not differ by treatment prescribed or whether they followed the prescribed treatment, the overall teething management by the paediatricians satisfied them.

**PIH48**

**DEVELOPING AN INSTRUMENT TO ASSESS PRODUCT PREFERENCE FOR TESTOSTERONE REPLACEMENT THERAPY**

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**OBJECTIVES:** Patients’ perceptions of products used for testosterone replacement therapy (TRT) may vary according to product attributes such as application site, duration of use and physical qualities. The objective of this study was to assess the domains associated with the preference for TRT products, to identify key themes and attributes, and to develop a patient-reported outcomes (PRO) instrument for use in clinical trials. METHODS: The study used a standard qualitative approach to develop a theoretical framework and to identify items and develop content for the PRO instrument. RESULTS: Items and themes gleaned from a literature review and expert opinion were used to develop a theoretical framework and a discussion guide. This guide was used by trained researchers to interview patients, who were experienced using TRT and voluntarily agreed and consented to participate in the research study using IRB-approved documents. Results from telephone interviews were transcribed using NVivo 9 qualitative analysis software (QSR International, Cambridge, MA) and classified according to TRT themes. Demographic and other data collected through the interview process were entered into a spreadsheet for descriptive analysis. RESULTS: The saturation of items and exhaustion of themes was accomplished by 58 male patients with an average age of 55.0 ± 1.3 years (22-69). Patients used TRT for an average of 183 ± 40.5 days, with approximately 50% of patients having experience with more than one form of TRT. Five patients participated in cognitive debriefing; the study revealed: ease of use and application, product characteristics, physiological impact, psychological impact, side effects, and treatment experience. CONCLUSIONS: Themes and items related to TRT use were in concordance with the theoretical framework developed in the study. The PRO instrument can be further developed for potential use in clinical trials.

**PIH49**

**PATIENT REPORTED OUTCOMES AS PRIMARY ENDPOINTS IN CONFIRMATORY CLINICAL TRIALS**

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**OBJECTIVES:** The purpose of this research was to determine the impact of patient-reported outcome (PRO) endpoint type (primary vs. nonprimary) on PRO-based labeling claims. This review examines PROs as both primary and nonprimary endpoints used to demonstrate treatment benefit of new molecular entities (NMEs) and biologic license applications (BLAs) in the United States (US) in the years 2000-2010. METHODS: Food and Drug Administration (FDA) Drug Approval Reports were reviewed to identify all approved NMEs and BLAs between January 2000 and December 2010. Generic products with tentative approvals were excluded. For all identified products with publically available drug approval packages, the medical review sections were reviewed to identify PRO endpoint use. Product label indicatations and clinical trial sections were reviewed to determine the number and type of PRO claims. RESULTS: A total of 264 NMEs/BLAs were identified. Of these, 63 NMEs/BLAs (24%) were granted PRO-based claims. The majority of product claims were for disease- or condition-specific signs and symptoms. Of the 63 products with PRO-based claims, the PRO was the primary endpoint for 54 (86%). All 54 PRO primary endpoints were signs and symptom evaluation; of these, 3 included a functioning measure as a coprimary endpoint. CONCLUSIONS: Successful PRO label claims are typically based on primary endpoints assessing signs and symptoms. Based on this research, studies with PROs dedicated as primary endpoints, compared with nonprimary, are more likely to facilitate positive regulatory review and acceptance of PROs in support of label claims.

**PIH50**

**FACTOR STRUCTURE OF THE NHANES PHYSICAL FUNCTION LIMITATION QUESTIONNAIRE AND ITS RELATIONSHIP WITH MUSCLE MEASUREMENTS IN US ELDERLY AGED 60-80 YEARS**

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**OBJECTIVES:** Physical function limitation and muscle wasting are commonly associated with many chronic conditions and the aging process. The National Health and Nutrition Examination Survey (NHANES) 2001-2002 included a physical function limitation questionnaire, as well as examinations measuring muscle mass and muscle strength. The factor structure of the physical function limitation questionnaire, however, is unknown. The aim of this study was to evaluate the factor structure of the questionnaire, and to examine the relationship between physical function and muscle measurements in the elderly in the United States. METHODS: Data from NHANES 2001-2002 participants aged 60-80 years (n = 1139) was used for this study. First, a maximum likelihood based exploratory factor analysis (EFA) with the Promax rotation (an oblique rotation) of the physical function limitation questionnaire items was implemented. The relationship among the identified questionnaire domains, muscle strength (as measured by isokinetic strength of the knee extensors), and muscle mass (as measured by appendicular skeleton muscle mass index) were examined using partial correlation coefficient (PCC) adjusted for age, gender, and percentage of body fat. RESULTS: The EFA produced a 3-factor solution for items measuring gross motor function, fine motor function, and social and acceptance of PROs in support of label claims.