treated patients, the generic SF-36 and DFS specific for patients with foot ulcers. Six other instruments were well validated and widely used, but their responsiveness was not documented and their sensitivity to change in RCTs was not consistent across the trials. CONCLUSIONS: Though several instruments have been identified, most of the them are specific for a subtype of diabetic population (type 1 or type 2, insulin-treated, patients with complications) and do not meet all criteria in regard to their psychometric properties. Further research is warranted to assess the sensitivity to change of diabetes specific patient reported outcomes instruments.

### PDB39

**DIABETIC PATIENTS’ PREFERENCE FOR INHALED INSULIN**

Prütz C1, Toft E2, Suchdev S1, Fält K1, Walrud B1

1Pfizer AB, Stockholm, Sweden, Sweden, 2Ersta Sjukhus, Stockholm, Sweden, Pfizer AB, Sollientuna, Sweden, 4KW-Partners, Stockholm, Sweden

**OBJECTIVE:** Assessment of diabetic patients’ Willingness To Pay (WTP) for inhaled insulin in relation to injected insulin.

**METHODS:** A questionnaire concerning preference and WTP for inhaled insulin was completed by 157 patients (age range, 20–65 years) in Sweden. Type 1 diabetic patients were receiving treatment with insulin (n = 40) and Type 2 patients were receiving treatment with either insulin as single therapy (n = 21), a combination therapy with insulin and anti-diabetic drugs (n = 46), or an oral anti-diabetic treatment with at least 2 oral drugs (n = 50). Patients were asked to assess their WTP for inhaled insulin by choosing from eight comparisons, at different prices. A Conditional Logit model was used to estimate the utility as a function of treatment and price. The WTP measure were the incremental price patients were willing to pay for inhaled insulin compared to injected insulin. **RESULTS:** Patients were willing to pay an additional 400SEK [50 US dollars] per month (on average) for inhaled insulin in comparison to injected insulin. Type 1 patient reported a lower marginal WTP than Type 2 patients. Type 1 patients were willing to pay an additional 219 SEK. Type 2 patients on insulin as single therapy, or on a combination therapy with insulin and anti-diabetic drugs, or treated with an oral anti-diabetic treatment with at least 2 oral drugs were willing to pay additionally 375SEK, 381SEK, 667SEK, respectively. At equal prices (500SEK) a total of 129 patients (85%) preferred insulin inhalation. At a large price difference, (300SEK vs 1400SEK), only 16% preferred inhalations. However, as many as 27 percent of patients on oral antidiabetic drug treatment still preferred inhaled insulin. **CONCLUSION:** In comparison to injected insulin 85% of patients preferred inhaled insulin at equal prices and patients are on average willing to pay 400SEK per month.

### GI DISORDERS—Clinical Outcomes

**PG11**

**HEPATITIS B IMMUNISATION FOR NEWBORNS OF HEPATITIS B SURFACE ANTIGEN-POSITIVE MOTHERS: A COCHRANE HEPATO-BILIARY GROUP SYSTEMATIC REVIEW AND META-ANALYSIS**

Lee CF

Tri-Service General Hospital, Taipei, Taiwan

**OBJECTIVES:** To assess the beneficial and harmful effects of hepatitis B active immunisation (vaccines) and passive immunisation (immunoglobulins) for newborns of positive hepatitis B surface antigen (HBsAg) mothers. Trials were identified through the trial registers of The Cochrane Hepato-Biliary Group, The Cochrane Neonatal Group, The Cochrane Library, MEDLINE, EMBASE, authors of trials, and industry until February 2004. **RESULTS:** Compared with placebo/no intervention, hepatitis B immunoglobulins (HBIG) significantly reduced hepatitis B occurrences (RR 0.50, 95% CI 0.41 to 0.60). Compared with vaccination alone, vaccination plus HBIG significantly reduced hepatitis B occurrences (RR 0.54, 95% CI 0.41 to 0.73). HBIG significantly reduced hepatitis B occurrences if administered within 12 hours of birth, but not within 24 or 48 hours of birth. No significant difference on hepatitis B occurrence was found between recombinant vaccine (RV) or plasma-derived vaccine (PDV) (RR 1.00, 95% CI 0.71 to 1.42). No significant differences on hepatitis B occurrences were found between high-dose PDV and low-dose PDV (RR 0.97, 95% CI 0.55 to 1.68) or high-dose RV and low-dose RV (RR 0.78, 95% CI 0.31 to 1.94). Hepatitis B vaccines and HBIG seem generally safe, but few trials reported on adverse events. In general, methodological quality did not significantly influence the results. **CONCLUSIONS:** Hepatitis B vaccination and HBIG within 12 hours of birth significantly reduces hepatitis B occurrences in infants of HBsAg-positive mothers.
CLINICAL: Loss of HBeAg is responsive to dose and duration in the treatment with interferon-α. A high-dose (≥5 MU) and regular-duration (16–24 weeks) interferon-α is effective than in clearing virological and serological markers. A dose ≥5 MU and a duration 16–24 week interferon-α is recommended to use.

MAJOR GI EVENTS AMONG ELDERLY CHRONIC USERS OF COX-2S AND NON-SELECTIVE NSAIDS, WITH/WITHOUT ASPIRIN

Wang J1, Mullins CD1, Naradzay JF1, Howard K2

1University of Maryland School of Pharmacy, Baltimore, MD, USA, 2Pfizer, New York, NY, USA

OBJECTIVES: The gastrointestinal (GI) risks associated with selective cyclooxygenase-2 inhibitors (COX-2s) versus non-selective non-steroidal anti-inflammatory drugs (NSAIDs) among arthritis patients are well documented in clinical trials. This study is to estimate the major GI risks among elderly chronic users of COX-2s versus NSAIDs, with/without aspirin (ASA), in clinical practice.

METHODS: A cohort study was conducted using secondary data from the GER logician database (Centricity EMR), which contained medical records of 3 million patients seen by 5,000 physicians across 27 states. Inclusion criteria: chronic use (2 or more medication mentions) of COX-2s or NSAIDs within 60 days between 1/1/1999 and 6/30/2003, 65 or older, no switch between COX-2s and NSAIDs during one-year follow-up or before a major GI event, defined as GI hemorrhage including melena (ICD-9 codes: 578.xx). Descriptive and multivariate logistic analyses were conducted to determine how major GI risks differed across chronic users of COX-2s alone, NSAIDs alone, COX-2s + ASA, and NSAIDs + ASA. The logistic analysis controlled for gender, age, pre- or post-index GI-harmful drug use, major and minor GI events in the year prior to index date, and prior GI-protective drug use.

RESULTS: The number of patients and the percent having major GI events during one-year follow-up period were as follows: COX-2s-alone 7,338 (1.73%); NSAIDs-alone 3,826 (2.06%); COX-2s + ASA 963 (1.77%); and NSAIDs + ASA 602 (2.66%). The multivariate logistic regression showed that compared to COX-2s-alone users, NSAIDs-alone and NSAIDs + ASA users had higher major GI risks (OR = 1.35, p = 0.04, 95% CI: 1.01–1.80; and OR = 1.68, p = 0.06, 95% CI: 0.99–2.86 respectively). COX-2s + ASA users had similar risks (OR = 0.96, p = 0.88, 95% CI: 0.57–1.61) to COX-2s-alone users. CONCLUSIONS: The major GI risk was highest among elderly chronic users of NSAIDs + ASA, followed by NSAIDs-alone. Only NSAIDs-alone users had a statistically significant higher risk than COX-2s-alone users. The addition of ASA did not significantly increase major GI risk among COX-2 users.