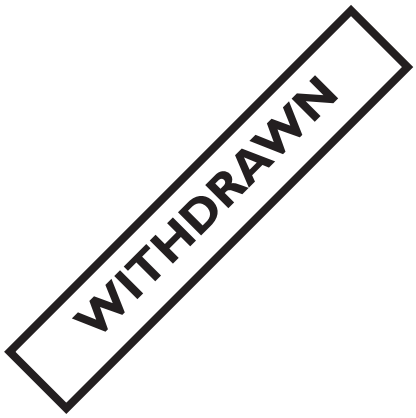
and this was more evident in patients with arthroplasty. The minimal score difference on 0–10 scale needed to detect clinical improvement (worsening) was 0.64(0.75), 1.03(0.67), and 0.29(0.72) for pain, physical function, and stiffness domain, respectively. **CONCLUSIONS:** WOMAC has good discriminative and evaluative properties. These properties provide an opportunity to measure new health technologies and other interventions in this cohort of patients with confidence. To benefit from the use of this measure as an interpretable one we need additional research in patients, particularly within clinical trials where other objective and interpretable measures are used.

PAR19



PAR20

BENEFIT-RISK-COST TRADE-OFF ANALYSES USING PATIENT PREFERENCES FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

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OBJECTIVE: To estimate the benefit-risk-cost (BRC) trade-off at the patient level, utilizing patient preferences for treatment choices in rheumatoid arthritis (RA). **METHODS:** Published patient preferences on 120 RA patients with mean disease duration of 8 years was used to conduct these trade-off analyses. Utilities (preferences) for 5 benefit characteristics (route, physician experience, onset, chance of benefit, bone erosions), 6 common adverse effects (injection site reaction, rash, oral ulcers, alopecia, nausea, diarrhea), 4 rare adverse effects (cancer, nephrotoxicity, hepatotoxicity, pneumonitis), and 1 cost characteristic (monthly co-pay) were estimated using adaptive conjoint analysis. The 16 characteristics were based on four treatment choices: methotrexate, gold, leflunomide, and etanercept. Based on the estimated utilities for the 16 characteristics, the marginal rates of substitution between pairs of characteristics were computed. **RESULTS:** Multiple BRC trade-off utilities were calculated and will be presented. A subset of three of these BRC trade-off utilities is presented below. The utility lost by patients switching from oral to subcutaneous injection was equal to the utility gained from: incidence of rash decreasing from 40% to 9.5%; nausea decreasing from 30% to 6.5%; diarrhea decreasing from 30% to 10.4%; or monthly co-pay lowered from $30 to $7.14. For chance of benefit versus onset trade-off, the range was from –0.086 weeks/% (0.086 weeks of delay in the onset of the drug, for a 1% increase in the chance of benefit) to –0.244 weeks/%. For onset versus diarrhea trade-off, the range was from –2.08%/week (2.08% reduction in the incidence of diarrhea, for a one week delay in onset) to –7.23%/week. **CONLCLUSIONS:** Patient preferences can be used to make explicit, the latent trade-off decisions made by patients at the characteristics level in arriving at treatment choice decisions. This study methodology can also be used to understand physician preferences for treatment choices.

DIABETES—Clinical Outcomes Studies

PDB1

RETROSPECTIVE STUDY OF INSULIN GLARGINE USE IN PREVIOUSLY INSULIN-NAIVE U.S. MANAGED CARE PATIENTS WITH TYPE 2 DIABETES

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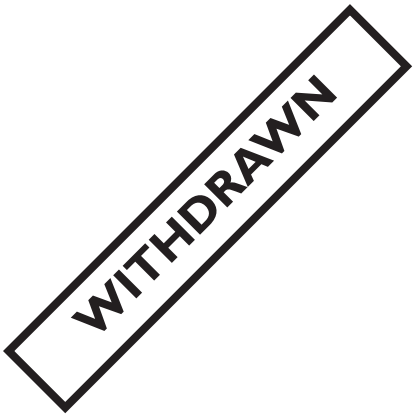
OBJECTIVES: Patient characteristics, treatment patterns, and clinical effectiveness were assessed for insulin naïve patients with type 2 diabetes (T2D) who initiated treatment with insulin glargine. **METHODS:** Administrative and pharmacy claims were linked with laboratory results from a large managed care database and were analyzed between May 1, 2001 and May 31, 2004. Patients with a diagnosis of T2D who were insulin-naïve prior to filling prescriptions for glargine were selected for analysis and followed for a minimum of 12 months. The initial claim for glargine served as the index date. Other antidiabetic therapy was assessed for the month prior to the index date. Glargine treatment patterns included persistence and concomitant medications. A subset of patients receiving HbA1c results both within 90 days pre- and no sooner than 60 days post-index periods were analyzed for HbA1c changes. **RESULTS:** A total of 936 insulin-naïve patients with T2D who initiated glargine therapy were identified. Prior to starting glargine, 50% of patients received no antidiabetic therapy, 21% received oral antidiabetic monotherapy, and 29% received combination oral therapy. Post-index, 20% of patients received glargine alone, while 80% received glargine in combination with short-acting insulin (38%) and/or oral antidiabetic agents (42%). The average length of glargine therapy was 185 days until a change in the index therapy occurred. In patients with both pre-and post-index values (N = 49), HbA1c decreased from 8.7% to 7.6% post-index (p = 0.0003). The average length of time between index and post-index HbA1c measurement was 216

days. Among patients with an HbA1c value post-index (N = 118), 28% reached the ADA target level of 7% or less. **CONCLUSIONS:** High pre-index HbA1c values may have contributed to the relatively low proportion of T2D patients achieving HbA1c goal after initiating glargine. This suggests an opportunity for earlier and more aggressive pharmacotherapy management of patients with T2D.

PDB2



PDB3

EARLY HEALTH TECHNOLOGY ASSESSMENT: CONTINUOUS GLUCOSE MONITORING FOR THE MAINTENANCE OF GLYCEMIC CONTROL IN INSULIN-REQUIRING TYPE 1 DIABETES

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OBJECTIVE: Patient-interactive, real-time continuous glucose monitors (RTCGMs) represent the future of diabetes management and have the potential to improve health outcomes and reduce diabetes-related complications. This assessment will evaluate the net health outcomes obtained in patients with insulin-dependent diabetes while using RTCGMs such as the FreeStyle Navigator™ (NAV), GlucoDay® S (DAY), Guardian® RT (GRT), DexCom™ STS™ and Long-Term Systems (DEX) and GlucoWatch® Biographer G2™ (GWG2), in comparison to standard self-monitoring of blood glucose. **METHODS:** Medline MeSH heading searches of the published peer-reviewed clinical literature identified all relevant studies since 2001. Technologies were evaluated based on their ability to provide clinically accurate glucose readings and improve glycemic control and overall health outcomes. **RESULTS:** The available data surrounding these devices is limited at this time because only GWG2 and GRT are currently FDA approved. GWG2 demonstrated less than adequate accuracy and a high false-positive rate (50–73%). DAY, GRT and DEX demonstrated acceptable overall accuracy in Clarke Error Grid studies (>95% zones A + B), however NAV is the most accurate of the RTCGMs (99% overall, 92.4% during hypoglycemia). Significant data surrounding the effects of DAY, DEX and NAV on glycemic control was not found, however GWG2 was shown to have no positive, and perhaps a negative, effect on glycemic control. Limited evidence with GRT revealed a decrease in the frequency and duration of hypo- and hyperglycemic excursions. GWG2 which reported excessive skin irritation in up to 76% of patients, often requiring discontinuation of use, however the other RTCGMs displayed no significant adverse event occurrence. **CONCLUSION:** Given the limited evidence presented in this assessment and based on its design and preliminary clinical data, it appears that NAV is the most favorable of the RTCGMs. Fulfillment of customary health technology assessment criteria will require FDA approval and additional data documenting successful implementation.

PDB4