OBJECTIVE: To assess the effect of short-term testosterone enanthanate (T) supplementation on health-related quality of life (HRQOL) in healthy, elderly males. **METHODS:** As part of a double-blind, placebo-controlled study, 22 healthy males ⩾ 65 years were randomized to receive a total of 4 doses of T 200 mg or placebo (P) intramuscularly every 2 weeks. HRQOL was assessed using the SF-36 and Psychological General Well-Being (PGWB) scales at baseline and after 8 weeks. Data was analyzed using unpaired and paired t-tests, adjusting for covariates. The study had 80% power to detect a 20-point difference in 4 of the SF-36 domains and the PGWB score; a *P*-value ⩽0.05 was considered statistically significant. **RESULTS:** The mean age in the T (n = 14) and P (n = 8) groups was 73.1 ± 3.1 and 70.1 ± 4.2 years, respectively. Baseline PGWB scores were similar between the groups (T:93.2,P:92.1). Baseline SF-36 scores were similar between the groups: physical functioning (PF) (T:93.9,P:82.5), role-physical (RP) (T:92.9,P:93.8), bodily pain (BP) (T:86.1,P:81.6), general health (GH) (T:84.4, P:76.9), social functioning (SF) (T:99.1,P:95.3), role-emotional (RE) (T:90.4,P:100.0) and mental health (MH) (T:84.7,P:76.0,); only vitality (VT) was significantly different at baseline (T:80.4,P:65.6; $P = 0.007$). After 8 weeks, SF-36 scores were similar between the groups:- PF (T:96.5,P:91.7), RP (T:92.3,P:100.0), BP (T:91.5,P:87.2,), GH (T:87.1,P:79.2), VT (T:80.0,P:74.2), SF (T:96.2,P:100.0), RE (T:89.7,P:100.0), MH (T:88.1, P:90.0). PGWB scores were not significantly different between the groups (T:95.0,P:95.8) and there was no significant change within each group in HRQOL scores over time. **CONCLUSION:** Healthy males ⩾ 65 years have high baseline HRQOL scores which are not enhanced by short-term testosterone supplementation.

PMW3

PRESCRIPTION DRUG USE DURING PREGNANCY: A CLAIMS ANALYSIS

Zenk HA[1], Carlson A[2]
[1]College of Pharmacy, University of Minnesota, Minneapolis, MN, USA; [2]Data Intelligence, LLC, Eden Prairie, MN, USA

The use of computerized databases to identify and follow large cohorts of pregnant women make it feasible to study trends in prescribing practices and to quickly identify defined cohorts of exposed pregnancies for further research. **OBJECTIVES:** This study had two purposes, to develop a methodology to identify pregnant women in an automated database and determine the type and extent of prescription drug use during a defined pregnancy period. **METHODS:** A retrospective analysis of prescription claims from an integrated managed care data base. The study population consisted of women, aged 12–50 years of age with a pregnancy indication during the period 10/12/96–12/31/98. Pregnant women were identified using ICD-9-CM diagnosis and procedure codes and CPT-4 codes. The pregnancy period was defined using date of service fields. **RESULTS:** 4,732 women were identified with a pregnancy during the specified time frame. 826 (17%) of these members had claims evidence of prescription drug acquisition. Each woman received on average 2 different medications during pregnancy and an average of 4.5 prescriptions. 25% of the prescription were agents defined as pregnancy class C (prescription anthihistamine agents, antiinfective agents and psychiatric medications such as lithium and phenothiazines), 4% were defined as pregnancy class D (antidepressant agents such as amitriptyline and nortriptyline, anticonvulsant agents), and 7% were classified as pregnancy class X (isotretinoin and estrogen preparations). Pregnancy class X poses the largest concern. 115 women were identified with claims for oral contraceptives that did not appear during the first or last month of the pregnancy period. One woman was identified with claims for isotretinoin during the pregnancy period. **CONCLUSIONS:** Information contained in the claims data provides evidence regarding the use of prescription drugs during pregnancy. Despite warnings in literature and public media drugs defined as pregnancy class X are acquired during the pregnancy period.

PMW4

MEASUREMENT PROPERTIES OF QUALITY OF LIFE INSTRUMENTS IN ERECTILE DYSFUNCTION (ED): A REVIEW OF PUBLISHED RESULTS

Emery MP[1], Kunle A[1], Marquis P[2], Sagnier PP[3], Kubin M[3]
[1]Mapi Research Institute, Lyon, France; [2]Mapi Values, Lyon, France; [3]Bayer, Slough, UK

Current trends in epidemiologic, economic and broader effects of ED have implications for both public health and patient QoL. Therefore evaluation of the impact of the condition as well as new and competing treatments must include assessment of QoL outcomes. Different measures have been developed for assessing the impact of ED and its treatments. Selection of one or more of these measures for clinical research and practice must be based on a careful comparison of published evidence of their psychometric validity including responsiveness. **OBJECTIVES:** To evaluate the psychometric properties and relevance of measures used for assessing QoL in published studies focusing on male sexual functioning in ill or well subjects. **METHODS:** The literature search of MEDLINE, EMBASE covered the period from 1966 to date using various terms including QoL, satisfaction, impotence and erectile dysfunction and was complemented by a search of bibliographic data from our Information Resources Center. **RESULTS:** 30 assessment tools have been systematically reviewed in detail for their measurement characteristics including psychometric properties. These were made up of 19 sexuality/ED-specific measures, 3 generic multi-dimensional QoL instruments, 7 psychological scales and one satisfaction measure. We found marked differences amongst instruments in terms of domains covered and extent of psychometric validation of measures in the same taxonomic category. In par-