compliance fractures in Spain. METHODS: Two alternative
models will be introduced here. One standard contingent valuation
model (CV), where mean values for willingness to pay
(WTP) for the treatment with BKP are obtained through a survey
including patients with primary osteoporosis. A new quality of
life adjusted wages model (QAW) is also introduced here. The
main assumption of this model is that a disease acts on individu-
als as a tax, where wages are deflected here by a quality of life
index (EuroQol 5-D) in the same way as a proportional income
tax. The burden of disease is given by this model in terms of an
equivalent variation or welfare changes in monetary terms. The
model avoids different kind of biases introduced in many times
by the CV approach and is a faster and more rigorous tool to find
welfare changes determined by diseases and their medical treat-
ments. RESULTS: A sample of 168 individuals who had been
asked about their WTP for BKP was used to develop the CV
model. A mean value for WTP of €3909 is revealed by the
sample. A sample of 300 patients 21 years of age or older
and both genders coming from a clinical trial designed by Kyphon,
was used to develop QAW model, here is that BKP determines in
the first month a yearly welfare gain of €2665, increased to
€3131 after 12 months. CONCLUSIONS: The results using CV
models and QAW model are similar in the first year of life. It can
be explained through a temporal downward bias introduced by
WTP responses that means that a patient doesn’t include in his
personal WTP an estimation of his life expectancy.

**MUSCULAR-SKELETAL DISORDERS—Health Care Use & Policy Studies**

**PMS67**

**HEALTH GAINS FOREGONE DUE TO THE SUSTAINED DELAY OF ADEQUATE UTILIZATION OF EVIDENCE-BASED TREATMENTS: THE CASE OF BISPONPHONATES FOR THE TREATMENT OF OSTEOPOROSIS**

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OBJECTIVES: Evidence-based guidelines recommend treatment
for postmenopausal women with osteoporosis to prevent frac-
tures. The study aims at determining since when this was known
and whether the utilization of bisphosphonates in Germany from
this point onward was adequate and to what extent health gains
might have been foregone due to a limited use of bisphosphonates.

METHODS: To determine since when the beneficial effect (pre-
vention of fractures) was known, cumulative meta-analyses of
randomized controlled trials derived from systematic reviews
were conducted. The evidence-base was considered as established,
when a significant (5%-level) reduction of fractures was observed
in trial populations combined in meta-analysis compared to thera-
pies without bisphosphonates. Utilization figures for bisphos-
phonates and epidemiological estimates where taken from published
sources. RESULTS: The hip/femur fracture risk was significantly
lower if treatment included bisphosphonates compared to treat-
ment without bisphosphonates (RR 0.62; 95%-CI 0.40–0.97 / RR
0.45; 95%-CI 0.23–0.90). In principal, this was known since
1995/1996. Utilization of bisphosphonates in 1996 was sufficient
for the continuous treatment of about 8,200 patients (440,000
patients in 2006). About 1.6 to 1.9 million patients annually might
have benefitted from treatment. About 22,800 fractures might
thus have been avoided, had all patients with potential benefit
continuously received bisphosphonates since 1996/1997. CON-
CLUSIONS: The delay in the wider use of bisphosphonates for
osteoporosis treatment has resulted in a considerable loss of
potential health gains in terms of avoided fractures. An arguable
lack of evidence for the expected benefit from bisphosphonate
therapy does not sufficiently explain this finding. Other factors
e.g. cost considerations) might have contributed to this result.
Limitations of the present analysis are primarily associated with
uncertainties of epidemiological estimates and the application of
study results to the entire patient population.

**PMS68**

**ANTI-TUMOUR NECROSIS FACTOR-ALPHA: INHIBITOR DOSE CHANGES IN RHEUMATOID ARTHRITIS PATIENTS IN A PROSPECTIVE PATIENT REGISTRY SETTING**

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OBJECTIVES: Real-world data on long-term dosing patterns in
first time anti-TNFα inhibitor treated rheumatoid arthritis
patients is lacking. Such data are important for the calculation
of treatment cost, especially for products where the label
allows for varying doses and frequency of administrations.

METHODS: The Dutch Rheumatoid Arthritis Monitoring
(DREAM) project is a longitudinal, multi-centre patient register
monitoring biologic DMARD usage in clinical practice since
February 2003. Patients meeting the Dutch reimbursement
criteria (DAS28 > 3.2, inadequate response to ≥2 DMARDs
including methotrexate, no prior bDMARDs) were assessed at
three-month intervals for 48 months. Dosing was determined by
the attending rheumatologist guided by the recommended
labelled doses (adalimumab 40 mg every other week, etanercept
25 mg twice weekly, infliximab 3 mg/kg at week 0, 2, 4, 8 and
every 8 weeks thereafter). Mean dose was calculated based on
the actual dose prescribed at each visit and the change over time
evaluated for each anti-TNFα. RESULTS: The mean baseline
doses for adalimumab (N = 374), etanercept (N = 432) and
infliximab (N = 325) were 39.9 mg/two weeks, 24.2 mg twice
weekly, and 3.4 mg/kg per eight weeks. Mean baseline DAS28
and HAQ ranged from 3.2–5.4 and 1.3–1.4, respectively.
Nearly one-third of infliximab patients were prescribed greater
than the labelled dose at baseline (32%, N = 105) compared to
2.5% and 0.2% for adalimumab and etanercept. At 12, 24,
and 48 months follow-up, mean doses were: adalimumab, 41.5,
43.3, and 45.7 mg/two weeks (48 months); infliximab, 4.3,
4.9, and 4.9 mg/kg/every eight weeks (48 months). Mean doses
in infliximab patients prescribed greater than the recommended
labelled dose at baseline were 4.7, 5.2, and 5.6 mg/kg at the
same follow-up intervals. CONCLUSIONS: Longitudinal patient
registry data from The Netherlands show a marked and
continued dose escalation in RA patients prescribed infliximab
as a first-line anti-TNFα when compared to either adalimumab
or etanercept.

**PMS69**

**PATTERNS OF MORBIDITY AND DIRECT COSTS ASSOCIATED IN THE OSTEOPOROSIS SPANISH POPULATION SETTING**

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OBJECTIVES: To determine the co-morbidity and direct cost
influence in patients with osteoporosis in a Spanish population
setting in usual medical practice. METHODS: We per-
formed a transversal retrospective study realized beginning from
registers of subjects older than ≥44 years appertaining to seven
centers of primary care (year 2,006). A control group without
osteoporosis was formed. Main measures: general (age, gender),
general co-morbidities and specific (ICPC-2), Charlson index
Abstracts

COST EFFECTIVENESS OF A NEW DRUG
OVERCOMING THE FINAL HURDLE: COMMUNICATING THE
PMT2

HAS THE QUALITY OF RANDOMISED CONTROLLED TRIALS
INCREASED WITH TIME: AN ANALYSIS OF DATA FROM 5
SYSTEMATIC REVIEWS?
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2Heron Evidence Development Ltd, Letchworth, UK

OBJECTIVES: When conducting systematic reviews of randomised controlled trials (RCTs), an important step is to critically assess the quality of included studies. As emphasis on sound trial design has increased over the years, we sought to establish how quality of studies included in systematic reviews is associated with the publication year of those studies. METHODS: We analysed the studies included in 4 large, clinical systematic reviews of randomised controlled trials conducted by Heron in the last 6 months. These covered 4 disease areas: oncology, hyperlipidaemia, anaesthesia, and serious bacterial infection. The data extracted included a critical appraisal of study quality based on means of quality scales. These were the Jadad scale, which assesses randomisation, blinding, patient attrition and reporting quality and gives a score from 1 (low) to 5 (high), and the allocation concealment grade, which assess whether allocation to treatment was adequately concealed. We analysed trends in both Jadad score and allocation concealment grade by year of publication, with stratification by disease area. RESULTS: A total of 291 trials were included in the analyses from the 4 reviews. Most of these were carried out between 1981–2008. The average overall Jadad score was 2.3, suggesting low overall trial quality. Jadad score increased from a mean of 1.4 over the period 1981–1986 to 2.9 over the period 2001–2006. Furthermore there was an increase in the percentage of high quality (Jadad score 4–5) trials—from 6% in 1981–1986 to 36% in 2001–2006. Only 3% of RCTs from the period 1981–1990 recorded adequate allocation concealment; this increased to 26% over the period 1996–2006. CONCLUSIONS: There was an observable increase in trial quality over the period analysed. However, the mean Jadad score, and the proportion of trials with adequate concealment of allocation remained low, even by 2006, indicating the need for continued attention to study quality.

POSTER SESSION III

CONCEPTUAL PAPERS & RESEARCH ON
METHODS—Clinical Outcomes Methods

COLLECTING REAL DATA FROM REAL PATIENTS
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OBJECTIVES: 1) To assess the willingness of patients to provide information about medical treatment, and 2) to practically demonstrate that useful information can be collected.

METHODS: Public acceptability towards reporting side-effects and efficacy of medical treatments was assessed by 1) online questionnaire, and 2) assisted questionnaire. Results from the first 137 respondents to the on-line questionnaire and 115 respondents to the assisted questionnaire are reported. A total of 110 leaflets were distributed inviting patients to log on to a dedicated website and provide information on post-vaccination symptoms. Information was gathered on the day of vaccination, two days later and at day eight. RESULTS: A total of 94% of interviewees were aware of the possibility of side effects. Of interviewees who had personal experience of side effects, 39% did not report them. The perceived principle conduit (81%) for reporting was to the physician. The motivating factors for reporting adverse drug reactions (ADR’s) in order of frequency was stated to be, ensuring medical safety of others (31%), ensuring their own future good health (28%) the advice of pharmacists/nurses (12%) and financial incentives if available (7%). A total of 73% reported willingness to report side-effects via the Internet. A total of 110 leaflets were distributed at an influenza vaccine clinic inviting patients to log on to an interactive website and provide information. 73 (66%) registered on the day of vaccination, 70 (96%) responded at day two and 66 (90%) at day eight. Statistics on pain and discomfort demonstrate that while the majority of patients have no pain, 8% experienced significant discomfort and 3% pain for greater than one hour. Of side effects reported, none required medical attention and the majority were self-limiting. CONCLUSIONS: Patients are willing to provide information about medical treatment via an interactive web-based system. This technique has potential for the conduct of naturalistic studies and for post-marketing surveillance.