TKR then declined steadily and at the end of 2006 were similar. Rates of THR/TKR peaked in all groups in Q1 2005. The rate three quarters decreased to 2.3%, 2.2%, and 2.3% respectively. Over the three quarters following the withdrawal of rofecoxib the average quarterly osteoarthritis of the pelvis, thigh, or lower leg (ICD-9-CM 715.5*6, 715*6) on a medical claim and who filled prescriptions for at least 90 days of therapy with rofecoxib, celecoxib (an alternative COX-2 inhibitor that continued to be available), or meloxicam (a patented, non-selective, nonsteroidal, anti-inflammatory drug). For each cohort, the quarterly number of total hip or knee replacement (THR/TKR) surgeries was tracked before the withdrawal of rofecoxib (Q1-Q3 2004) and subsequent to withdrawal (Q4 2004-Q4 2006). RESULTS: The study cohorts included 31,551 rofecoxib users, 38,388 celecoxib users, and 7,007 meloxicam users. During the three quarters prior to the withdrawal of rofecoxib the average quarterly growth over Q1 2004 was 45% for rofecoxib, 38% for celecoxib, and 71% for meloxicam. Quarterly rates of THR/TKR were 4.8668 (0), Type of surgery (os/ap): 1.7599 (0.0198), Hospital type (university/capital): 0.4656 (0.0032), Types of co-morbidities (ICD): C00-C07: 3.0667 (0.0006), E10-E16: 1.4339 (0.0458), F00-F99: 2.0614 (0.0003), I20-152: 4.2459 (0), I70: 1.5504 (0.0013), J00-J22: 5.2241 (0), L89: 1.9277 (0.0334). CONCLUSIONS: Without differentiating co-morbidities, higher age, male gender, lateral fracture, longer surgical delay, osteosynthesis surgery and lower progression level of primary treatment proved to be of higher risk for one year mortality. With the differentiation of co-morbidities the role of surgical delay became weaker, while certain co-morbidities had higher risk for one year mortality.

**PM513**

**IMPACT OF VIOXX WITHDRAWAL ON VOLUME OF TOTAL HIP AND KNEE REPLACEMENTS**

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OBJECTIVES: To explore the impact of the October 2004 withdrawal of rofecoxib on the use of surgical treatment for osteoarthritis, specifically total hip and knee replacement.

METHODS: Patients were selected from the MarketScan databases, which during January–September 2004, had a diagnosis of osteoarthritis of the pelvis, thigh, or lower leg (ICD-9-CM 715.5*6, 715*6) on a medical claim and who filled prescriptions for at least 90 days of therapy with rofecoxib, celecoxib (an alternative COX-2 inhibitor that continued to be available), or meloxicam (a patented, non-selective, nonsteroidal, anti-inflammatory drug). For each cohort, the quarterly number of total hip or knee replacement (THR/TKR) surgeries was tracked before the withdrawal of rofecoxib (Q1-Q3 2004) and subsequent to withdrawal (Q4 2004-Q4 2006). RESULTS: The study cohorts included 31,551 rofecoxib users, 38,388 celecoxib users, and 7,007 meloxicam users. During the three quarters prior to the withdrawal of rofecoxib the average quarterly incidence of THR/TKR in these three cohorts was 2.2%, 1.9%, and 2.0% respectively. Over the three quarters following the Vioxx withdrawal, these rates increased to 2.8% for rofecoxib, 2.4% for celecoxib, and 2.6% for meloxicam, then in the next three quarters decreased to 2.3%, 2.2%, and 2.3% respectively. Rates of THR/TKR peaked in all groups in Q1 2005. The rate of growth over Q1 2004 was 45% for rofecoxib, 38% for celecoxib, and 71% for meloxicam. Quarterly rates of THR/TKR then declined steadily and at the end of 2006 were similar to the beginning of 2004. CONCLUSIONS: These results suggest that the withdrawal of rofecoxib had the result of temporarily increasing the use of THR/TKR to treat osteoarthritis. This effect was seen not only among rofecoxib users, but also patients receiving other drugs for whom a major non-surgical treatment option was removed.

**PM514**

**NEW STRATEGIES IN THE TREATMENT OF RHEUMATOID ARTHRITIS PATIENTS IN ITALY: A BUDGET IMPACT ANALYSIS**

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OBJECTIVES: To evaluate the impact on Italian National Health Service (NHS) budget of the introduction of Rituximab (RTX) and Abatecept (ABAT) in the treatment of rheumatoid arthritis (RA) patients not adequately responding to anti-TNFα therapies.

METHODS: First, RA patients eligible to second-line biologic treatments and the available strategies for their management were identified and quantified; second, costs associated to the different alternatives were estimated; finally, the impact on the NHS budget was estimated using a cohort simulation based on a Markov chain with 1-year cycles and a time horizon of 10 years. Only direct medical costs were considered, including drug acquisition, administration, incidental premedication and monitoring tests and exams.

RESULTS: Italian RA patients eligible to second-line biologic therapies were estimated in about 1,300 per year. Three strategies were identified as available: the currently used strategy, based on the switch between anti-TNFα therapies, and two innovative strategies based on RTX and on ABAT. The simulated effect of a progressive replacement (16%, 50%, and 100% at years 1, 5, and 10, respectively) of the current strategy with the two new strategies yielded the following results: RTX therapy induces a decrease of costs of 1.16 million Euro (~7.1% with respect to current strategy), 4.91 (~7.7%) and 4.94 (~5.3%) at years 1, 5, and 10, whereas ABAT therapy induces an increase of 0.6 million Euro (~3.7%), 5.43 (~8.5%) and 20.62 (~22.2%). In the direct comparison between the two new strategies RTX results less expensive (10.4%, 14.9% and 22.5% at years 1, 5, and 10, respectively). CONCLUSIONS: The introduction of new therapies in the treatment of Italian RA patients represents a valuable option. The use of RTX is expected to induce a reduction in costs while ABAT probably would produce an increase. These results are preliminary, more detailed data on the population and observed costs are needed.

**PM515**

**LEFLUNOMIDE IN THE TREATMENT OF RHEUMATOID ARTHRITIS IN POLAND—A BUDGET IMPACT ANALYSIS**

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Leflunomide is recommended as an effective therapeutic option in patients with methotrexate-resistant rheumatoid arthritis. Its use in Poland is limited as it is available only in Therapeutic Programs. OBJECTIVES: To assess the potential impact on the Polish health care budget of introducing leflunomide reimbursement in rheumatoid arthritis in Poland.

METHODS: Analysis was conducted from the perspective of National Health Fund. Only direct medical costs including costs of leflunomide, DMARDs, NSAIDs, steroids, outpatients and hospitalizations were considered. Data from Central Statistical Office, Polish Ministry of Health, National Health Fund, Institute of Rheumatology, IMS Health, National Health Fund, Institute of the Health Services, Warsaw, Poland.

Leflunomide reimbursement would impose additional financial burden on the Polish health care system. In costs while ABAT probably would produce an increase. These results are preliminary, more detailed data on the population and observed costs are needed.