24 weeks received a 50 mg BW maintenance dose, and 23% of infliximab patients received infusions every 6 weeks. Reasons for dose increase included higher severity of disease, longer disease duration, loss of efficacy, overweight, joint involvement, higher number of systemic therapies received. CONCLUSIONS: Real-life dosing of psoriatic biologics does not always conform to the posology recommended in the product label, especially for high need patients. About 20% of patients being treated with a TNF-alpha-inhibitor seem to need a higher non-standard dose.

THE IMPACT OF POTENTIAL PILL SPLITTING ON GENERIC AND BRANDED FINASTERIDE UPTAKE
Nicholas E, Wiederkehr DP, Doyle J
Quintiles Global Consulting, Hawthorne, NY, USA
OBJECTIVES: Finasteride is indicated for the treatment of male pattern hair loss at 1 mg strength and for male symptomatic benign prostatic hyperplasia (BPH) at 5 mg strength. While the male pattern hair loss indication exclusivity does not expire until 2013, the BPH indication expired in 2006. Patients have been known to purchase generic finasteride in 5 mg strength and split the pills into quarters as a less expensive alternative to the branded 1 mg dose. The objective was to examine the uptake of generic finasteride in relation to the prescribing volume of branded finasteride for the treatment of male pattern hair loss to determine the impact of potential pill splitting on generic uptake and branded prescribing volume. METHODS: Generic and branded finasteride were selected as case products. From 1992 to 2010 the volume of prescriptions (TRx) were collected monthly using SDI’s VONA databases and grouped according to branded and generic sales. RESULTS: Sales of generic finasteride significantly increased immediately after launch. The competitive average growth rate (CAGR) of TRx of branded 5 mg finasteride between 1992 and 2006 was 23.29%. Meanwhile, the CAGR of generic 5 mg finasteride from 2006 to 2010 was 96.17%, signaling an aggressive growth trend. Interestingly, the sales of branded 1 mg finasteride were not impacted as substantially by sustained steady growth with a CAGR of 2.49% over the 10 years since generic launch. CONCLUSIONS: One hypothesis as to the immediate growth of generic finasteride after launch can be attributed to pill splitting; much of the volume increase was due to patients purchasing the much less expensive generic 5 mg finasteride and quartering the pills. However, if pill splitting did occur, it did not appear to impact sales of branded 1 mg finasteride as demonstrated by a maintained steady growth in TRx. This suggests that patients who pill split may not have been prior users of branded 1 mg finasteride.

COST COMPARISON OF PATIENTS WITH CHRONIC HAND ECZEMA COVERED BY STATUTORY VS. OCCUPATIONAL HEALTH INSURANCES IN GERMANY
Djennet T, Augustin M, Parwez S, Posthumus J, Kuesner D
University Heidelberg, Heidelberg, Germany; University Clinics of Hamburg, Hamburg, Germany; Basilea Pharmaceutica, Basel, Switzerland
OBJECTIVES: In Germany, patients with chronic hand eczema (CHE) can either be treated within the statutory health insurance system, or if CHE is work-related CHE in the system of occupational health insurances. The study objective was to analyze the cost of CHE between both systems. METHODS: The survey was conducted in 24 practices in the statutory health insurance system and 2 specialized centers of the occupational health insurances. Patients with CHE refractory to potential topical treatments were included. Patient characteristics (status and resource use were elicited from patients and physicians. Costs were evaluated from the societal perspective (using insurance specific tariffs). Regression models were employed to compare the costs across both data sets. RESULTS: A total of 223 patients in the statutory health system and 87 patients in the occupational health insurance system were included in this study. The patients’ severity was similar across both samples. The yearly direct and indirect costs per patient are €1742 and €386 in the statutory health insurance system as well as €3509 (€2534 according to statutory health insurance tariff) and €3422 in the occupational health system. The indirect costs are more pronounced among patients with work-related CHE, a comparison of direct and indirect costs reveal higher costs for patients covered by occupational health insurances (P = 0.01); however, no cost differences between both systems can be detected after controlling for treatment stage and referral differences. CONCLUSIONS: Differences in the costs between both systems can be explained by different treatment mix, as direct costs are similar across treatment stages. As a result of longer absences from work, the indirect costs of patients with work-related CHE are higher. This may lead to the use of more effective and costly treatment strategies in this patient group.

ECOLOGICAL ANALYSIS OF CATARACT SURGERY IN EUROPE: AN ANALYSIS OF HOSPITAL DATABASES AVAILABLE IN 11 COUNTRIES
Deo M, Lafuma A, Berdeaux G
CEMMA-EVAL, Bourg la Reine, France; Alcon France, Rueil-Malmaison, France
OBJECTIVES: Cataract surgery is one of the most efficacious medical strategies and one of the most frequently performed operations in developed countries. Organization for Economic Co-operation and Development (OECD) collects information on this topic but their data are not updated often. The aim of this study was to estimate the number and costs of cataract surgeries performed in 14 European countries and the potential costs associated with astigmatism. METHODS: Cataract surgery numbers were estimated from available databases. Costs associated with cataract surgery were based on official tariffs of local health care systems. The number of surgeries and the costs per 100,000 people were estimated for each country to allow comparisons. Astigmatism related costs were also explored. This survey was carried out in 14 European countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, The Netherlands, Portugal, Spain, Sweden, and the UK. RESULTS: Information was fully available in 10 countries and partly available in OECD statistics. Cataract surgery rates were in the range of 444 to 1,006 operations per 100,000 people in the countries with complete information. All the countries were using a DRG system for costs and tariffs. Costs of operations were highly dependent on complications, type of surgery, and surgical setting (outpatient or inpatient). Average cost of surgery ranged across the countries from €875 to €2000. Average cost per inhabitant was estimated at between €5 and €15 per year. Astigmatism associated complications were never taken into account. CONCLUSIONS: Cataract surgery is performed in a large part of the European population with variations across countries. Further research needs to be conducted to explain differences between countries.

CATARACT SURGERY GUIDELINES IN EUROPE: A LITERATURE REVIEW AND DOCUMENT SEARCH IN 13 COUNTRIES
Javaint V, Lafuma A, Berdeaux G
CEMMA-EVAL, Bourg la Reine, France; Alcon France, Rueil-Malmaison, France
OBJECTIVES: Cataract surgery is one of the most efficacious medical strategies and one of the most frequently performed operations in developed countries. The aim of this survey was to establish an assessment of the available guidelines for cataract surgery in Europe. METHODS: The search was performed with a two steps design. A classical literature search was performed using the method elaborated by the French Haute Autorité de Santé directly through the Internet. A second step was to interview local experts to identify grey literature in local languages that could be available through local health authorities or medical societies. This survey was carried out in 13 European countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, The Netherlands, Portugal, Spain, Sweden, and the UK. RESULTS: The classical literature search identified 15 documents that could be considered as guidelines on cataract surgery. They were mainly written in English; only one originated in Europe. General guidelines (n = 9) considered the initial check-up and indications for cataract surgery, surgical techniques and follow-up. Specific guidelines were found covering the type of implants (n = 1), surgical technique (n = 1) and the anaesthesia technique (n = 4). This latter group was mainly extracted from the Cochrane database. The second step of the research identified 10 local guidelines in 7 European countries. These guidelines were rarely complete (n = 2) and envisaged some specific aspects of the operation (n = 8) or the implants (n = 2). CONCLUSIONS: Guidelines on cataract surgery are available at an international level but are rarely provided at a country level in Europe.

SENSORY SYSTEMS DISORDERS – Conceptual Papers & Research on Methods

USE OF CALL CENTRE METHODOLOGY TO COLLECT QUALITY OF LIFE (QOL) DATA IN A CLINICAL TRIAL: A CASE STUDY OF PATIENTS WITH DIABETIC MACULAR EDEMA (DME)
Lafuma A, Alcon A, Lau P, Wallace S
Pfizer Ltd, Walton, UK; Pfizer Inc, San Diego, CA, USA; Quintiles Ltd, UK, Livingston, Scotland, UK
OBJECTIVES: QoL data collected in clinical trials traditionally involves self-report or face to face interviewer-administered questionnaires. The former may result in missing data/errors; the latter requires trained interviewers, possibly adding variability to the data collected (when multiple sites are involved) or bias in terms of social desirability. To improve the quality of data collected in a clinical trial for DME, we employed a centralised call centre methodology. METHODS: QoL data were collected in a large multicenter trial, NCT00605280, evaluating the safety and efficacy of pegaptanib sodium in patients with DME. An interface between the trial database and the independent call centre was established. Once subjects entered the trial, subject agent received subject contact and visit details from the trial database. The call agent then interviewed the subject and subject information and completions were sent to the trial database weekly. RESULTS: The two QoL measures (National Eye Institute Visual Function Questionnaire 23 and EuroQol Group’s EQ-5D questionnaire) had high completion rates; 99.8% of completions were recorded directly into the call centre database. The status of the QoL visit was recorded in the call centre database. The status of the QoL visit and information and completions were sent to the call centre database weekly. RESULTS: The two QoL measures (National Eye Institute Visual Function Questionnaire 23 and EuroQol Group’s EQ-5D questionnaire) had high completion rates; 99.8% of completed interviews included both questionnaires (57% successfully completed on initial attempt, 23% on the second attempt of contacting the subject). Only 4% of data were missing; 26 minutes was the average completion time. CONCLUSIONS: This call centre methodology resulted in high questionnaire completion and little missing data. This approach demonstrates robustness and offers a feasible alternative for questionnaire administration, particularly in visually impaired people. Administration in the subject’s home may be advantageous and centralised interviewers (instead of site interviewers) potentially reduced the variability in questionnaire response. Further research comparing methods is indicated.