exposure to this drug was available. With data accumulated till that moment a Relative Risk of 4.46 (95% Confidence Interval: 2.84–6.72) was found.

Conclusions: This analysis shows that by using the EU-ADR database network a strong signal concerning rofecoxib and acute myocardial infarction could have been detected much earlier than rofecoxib withdrawal. Whether this holds prospectively for other signals will depend on the incidence of the event, the level of exposure and the lag time.

370. Drug Intoxication in Patients Registered for Liver Transplantation for Acute Liver Failure: Results from the 7-Country SALT Study

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Background: Intentional or non-intentional drug overdose may cause acute liver failure (ALF) leading to transplantation.

Objectives: To evaluate drug overdose cases identified in the SALT study.

Methods: SALT study was a multicentre, case-population study performed in France, Greece, Ireland, Italy, Netherlands, Portugal, and UK between 2005 and 2007 in adults. Data on ALF cases were sought through liver transplant registries and hospital records. ALF cases were classified as (1) with an identified clinical cause (were not further considered for drug exposure), (2) exposed to drugs (including herbal and homeopathic medicines) within 30 days of index date (ID, initial symptoms of liver disease). Drug-exposed cases were again subdivided into (1) acute drug intoxication (ADI), with or without suicidal intent, (2) non-ADI. Demographic, clinical, and drug use data in the 30 days prior to ID were collected for all drug-exposed ALF cases. Drug-exposed cases of ALF were assessed individually by a case adjudication committee using WHO causality scale.

Results: Fifty-two (91%) of the 57 eligible transplant centres contributed data. A total of 9,479 cases registered for transplantation at the contributing centres, of which 600 were ALF, and 301 were exposed to a drug within 30 days prior to ID. Of these, 114 were ADI (72 intentional, 10 non-intentional, 32 intentionality not clearly defined). ADI was responsible for 20% of all cause ALF in the seven participating countries; the highest in Ireland (52%), followed by the UK (28%), France (18%), the Netherlands (8%), Italy (1%). No ADI cases of ALF were identified in Greece and Portugal. ADI were mostly females (61%), mean age 33.6 ($\pm$ Std 10.9) years. One hundred eleven (97%) of the 114 ADI cases had been exposed to paracetamol, all had the causality score possible, probable or highly probable. Thirty-one (27%) ADI cases were exposed to antidepressants, and 30 (26%) to psycholeptics. For the three non-paracetamol cases, causal drugs were benzodiazepin derivatives + opioids, ectasy, and diclofenac + iron.

Conclusions: Paracetamol overdose with or without suicidal intent represented 97.4% of all intoxication drug-related ALF.

371. Effect of Regulatory Measures on Nimesulide Utilization in the Lisbon Region

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Background: Nimesulide has been associated with increased risk of hepatotoxicity. This prompted regulatory action by the European Medicines Agency. The following measures were applied in Portugal in 2011: change in product approved indications (January), a "dear doctor" letter (March), and removal of packages for therapies longer than 15 days (up to June).

Objectives: To quantify the effect of regulatory measures in nimesulide utilization in the Lisbon region.

Methods: We conducted a retrospective time-series analysis of billing records in the National Health Service in the Lisbon region (4.4 million patients). We gathered data on all oral non-steroidal anti-inflammatory drugs (NSAIDs) between January 2006 and November 2011 with monthly intervals. The main outcome was the proportion of nimesulide daily defined doses (DDD) billed for the total of oral NSAIDs (market share). We used autoregressive integrated moving average (ARIMA) to create a forecasting model from utilization data up to January 2011 (first regulatory measure), and predicted nimesulide utilization in the following months with 95% confidence intervals, which was then compared with actual data.

Results: Nimesulide was the NSAID with most DDDs billed from January 2006 to March 2007, with an average 22.3% market share (203.7 DDDs/1000 patients/month). Utilization dropped suddenly between April and June

2007 (at that time the drug was removed from market in Ireland) and in the last semester of 2007 it had a market share of 14.2%. We therefore included into our model only data from June 2007 to January 2011. Best fit was achieved with an ARIMA(0, 1, 0) (1, 0, 0) model (R-squared 0.915; Ljung-Box Q statistic p = 0.957). Observed nimesulide market share decreased from 13.1% in January 2011, to a nadir of 6.6% in July, and then slowly increased to 7.3% in November (fifth in NSAID market share that month). Observed data fell and remained below the lower confidence limit of our model from April onwards.

Conclusions: Upon regulatory intervention, nimesulide utilization was significantly reduced in a manner not explained by chance or previous trends. However, it remained a highly used NSAID and market share seems to be increasing.

372. Are Low-Cost Generic Prescriptions Faithfully Captured in United States Pharmacy Claims Databases?

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Background: Many chain pharmacies in the United States have introduced four-dollar generic drug programs beginning in September 2006, representing some of the most widely used generic drugs. Because patients may pay out-of-pocket for medications purchased through these programs, concerns have been raised that some commercial pharmacy claims databases may not capture low-cost generic prescriptions.

Objectives: To evaluate the potential for missing drug claims after the initiation of the four-dollar generic program, by studying secular trends in warfarin filling among patients receiving regular international normalized ratio (INR) tests.

Methods: The MarketScan Research Database, a large national insurance database, was examined for the completeness of warfarin drug claims. Because patients on warfarin receive regular INR tests, and INRs are not regularly ordered on patients without concomitant use, this drug was ideal to examine pharmacy claims completeness. In each calendar quarter from 2003 to 2009, continuously-enrolled patients with at least two atrial fibrillation diagnoses and at least two outpatient INR tests were identified. Patients were also required to have at least six total months of continuous eligibility, be without hepatic dysfunction, and have pharmacy insurance benefits, filling at least one prescription in the quarter. Trends in the percentage of patients with prescription claims for generic warfarin and brand-name Coumadin were compared per calendar year and quarter to assess the policy's effect.

Results: Out of 377,879 patient-quarters, the percentage of drug claims per patient for each calendar quarter decreased slightly from 85.85% (95% CI: 84.97, 86.73) in 2003 quarter 1–84.12% (95% CI: 83.45, 84.79) in 2006 quarter 3. After the programs' introduction, the percentage decreased more substantially to 80.67% (95% CI: 80.15, 81.19) in 2009 quarter 4. Calendar years showed parallel trends and similarities across demographic characteristics.

Conclusions: Our study showed a very small decrease in warfarin filling after the introduction of the low-cost generic prescription drug programs, suggesting that the problem of missing claims is at worst small.

373. Extraction of Electronic Health Record Data in a Hospital Setting: Comparison of Automatic and Semi-Automatic Methods Using Anti-TNF Therapy as Model

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Background: Electronic health records (EHR) with integrated prescribing modules offers new possibilities to monitor drug utilization using the individual patient as the unit of analysis. Several studies have demonstrated extractions of drug information in primary care. There is limited experience and methods for extractions of drug therapy data in the hospital setting. Since most new drug therapies are introduced in hospitals there is a need to develop methods to study the quality and safety of drug therapy in the hospital setting.

Objectives: We evaluated the completeness and consistency of a generic automatic vs. a semi-automatic model for studying drug prescribing and dispensing of the TNF inhibitor infliximab (TNFi) across different diagnoses using a hospital based EHR-system.

Methods: This generic model builds on clinical information generated at Karolinska University Hospital (Stockholm, Sweden) by its EHR-system TakeCare®. Using two different extraction procedures, all administered infusions of infliximab during 2007–2010 were extracted from a relational database linked to the EHR-system. Extracted data included encrypted personal identity number, date of birth, sex, time of prescription, time of administration, healthcare units, prescribed and administered dose, time of admission and time of discharge. The primary diagnosis