(BADBIR) is a longitudinal, observational, web-based pharmacovigilance register of patients with moderate-to-severe psoriasis. Patients are currently recruited from 153 dermatology centres in the UK and Republic of Ireland. The aim of BADBIR is to explore the long-term safety of biologic compared to conventional systemic therapies. Patients registered in 10 centres in Wales were flagged with the National Health Service Wales Informatics Service (NHS WIS) to maximise the capture of overnight hospitalisations.

Objectives: To investigate the overlap in reporting of overnight hospitalisations to BADBIR and NHS WIS.

Methods: Data from 27/12/2007 to 28/12/2014 on 490 patients were received from NHS WIS. Overnight hospitalisations occurring after the start date of BADBIR registration therapy were classified as serious adverse events. Events were cross-referenced for admission and discharge dates (±7 days), and ICD-10 codes from NHS WIS with qualitative descriptions in BADBIR.

Results: Of the 490 patients flagged, 86 overnight hospitalisations for 62 patients were recorded with BADBIR and 244 overnight hospitalisations for 120 patients recorded with NHS WIS. 51 patients with overnight hospitalisation were reported in both datasets, but only 62 of 73 overnight hospitalisations were matched to events already on the BADBIR database. In total, 268 overnight hospitalisations were recorded for 131 patients.

Conclusions: The findings suggest that the reporting of overnight hospitalisations is more complete in NHS WIS than in BADBIR. Possible reasons contributing to the substantial proportion of missing overnight hospitalisations include: lag time in data entry (mean 283 days between admission date and event reporting to BADBIR; unknown for NHS WIS), admission to hospitals remote from the dermatology recruiting centre, patient recall bias, and incomplete information from recruiting centres. Failure to use linked sources may lead to underestimated risks of overnight hospitalisations.

937. NOACs Replace VKA as Preferred Oral Anticoagulant Among New Patients

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Background: In 2012, around 400,000 patients in the Netherlands were treated with vitamin K antagonists (VKA) for thromboembolic diseases. Since 2011, non-VKA oral anticoagulants (NOACs) have been available. NOACs do not require frequent INR monitoring and cause less bleeding, which benefits patients, but also imposes a risk of reduced therapy adherence.

Objectives: The objective of this study is to describe uptake of and patient compliance with NOACs in The Netherlands between July 2011 and October 2016.

Methods: We analysed prescription data for 247.927 NOAC and/or VKA patients across 560 pharmacies.

All patients who received at least one prescription of either VKA or NOACs between 1 July 2011 and 30 September 2016 were included in the study.

Our database contained (not exhaustive) the following information about the prescriptions: dispensed medication and quantity, dispensing date, prescribed dosage and prescriber type, patient age and gender.

We used these data to describe patient profiles, uptake of NOACs among new naïve patients and switch of patients between VKA and NOACs. We developed an algorithm to classify patients as new naïve starters, switcher or repeat patients.

We calculated therapy compliance as the percentage of days covered (PDC). To obtain reliable results, in our PDC calculations we included only patients with a time period of at least 12 months between their first and last prescription.

Results: During the studied period the share of NOACs in oral anticoagulants has grown to 57% of prescriptions to new patients. More than 70% of new NOAC users were new naïve patients and around 26% switched from VKA. The overall share of NOACs among starters is largest in the group of

patients of 50–80 years. Calculated percentages of days covered (PDC) for NOAC patients show that 87% of all users were compliant.

Conclusions: NOACs have overtaken VKA as the major treatment prescribed to patients starting on oral anticoagulants, and the number of starters on VKA is at present decreasing. We expect that almost all oral anticoagulants prescribed to new patients will be NOACs. NOAC users are in general compliant with therapy. This may provide additional confidence to physicians in prescribing NOACs instead of VKAs.

938. Evaluation of Potential Off-Label Prescribing of Dabigatran Etexilate in France, Denmark, and the United Kingdom and Associated Methodological Challenges

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Background: In the context of approval of the atrial fibrillation (AF) indication for dabigatran etexilate, as a follow-up measure the sponsor and EMA agreed to evaluate potential off-label use of dabigatran in Europe. The methodological challenges of using data sources with different types of clinical data had not been studied in detail.

Objectives: Discuss estimated prevalence of potential off-label use and associated methodological challenges.

Methods: Observational, cross-sectional study on dabigatran in three databases with different types of clinical information available: Cegedim Strategic Data Longitudinal Patient Database (CSD-LPD), France (cardiologist panel, n = 1,706 [FR-1]; general practitioner panel, n = 2,813 [FR-2]; primary care information); National Health Databases, Denmark (n = 28,619; hospital episodes, dispensed ambulatory medications [DK]); and Clinical Practice Research Datalink (CPRD), UK (linkable to Hospital Episode Statistics [HES], n = 2,150 [UK-1]; not linkable, n = 1,285 [UK-2]; hospital and primary care data were available for HES-linkable patients) (Aug 2011-Aug 2015). Two definitions were applied to estimate potential off-label use based on either recorded diagnoses or proxies: a broad definition of on-label prescribing using codes for disease indication (e.g., AF) and a restrictive definition excluding patients with conditions for which the drug is not indicated (e.g., valvular AF).

Results: Key methodological challenges: availability of detailed hospital and primary care clinical information impacted results observed across data sources. Limited information available likely led to overestimation of off-label use, particularly in CSD-LPD, and may explain the disparate prevalence estimates across countries. Estimates under the broad definition: UK-1 5.7%, UK-2 11.5%, DK 17.1%, FR-1 24.1%, FR-2 34.0%; and under the restrictive definition: UK-1 17.4%, UK-2 25.6%, DK 29.1%, FR-1 37.5%, FR-2 44.1%. No diagnoses potentially related to anticoagulant use could be identified in a large proportion of potential off-label users.

Conclusions: Results need to be interpreted cautiously due to limitations in the availability of data (no primary care data in Denmark; no hospital data in France). In this context, CPRD HES-linkable estimates are likely to be the most accurate. Availability of detailed clinical data is crucial for this type of research.

939. Baseline Patient Characteristics Associated with Non-Adherence to Dabigatran and Rivaroxaban in Nonvalvular Atrial Fibrillation New Users. A French Nationwide Cohort Study

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Background: The efficacy of direct oral anticoagulants (DOACs) in nv-AF patients is closely dependent on strict adherence in clinical practice.

Objectives: To identify patient characteristics associated with non-adherence to dabigatran and rivaroxaban in nonvalvular atrial fibrillation (nv-AF) new users.