2.81), 1.21 (0.45, 3.26), 0.75 (0.27, 2.05) in a record linkage DS and 0.51 (0.11, 1.50), 1.54 (0.52, 4.61), 0.53 (0.19, 1.52), 0.40 (0.14, 1.21) in a GP DS. For fever, the corresponding IRs in the same DSs were 30.17 (27.09, 33.51), 90.19 (69.60, 130.18), 13.25 (9.54, 18.40), 17.37 (12.51, 24.15) and 90.28 (82.75, 98.31), 66.09 (29.39, 148.61), 34.34 (22.58, 52.24), and 43.15 (28.36, 65.67).

Conclusions: For well-captured events in a DS, such as FS in the record linkage DS, derivation of IRs using estimates from DSs lacking data on FS (GP DSs) produced a risk period IR inconsistent with that observed. In a GP DS, observed IRs for symptoms such as fever differed from IRs derived via multiplication by meta-IRRs which included record linkage DSs. This shows the importance of studying database heterogeneity before parameter derivation. The similarity of derived IRs using baseline vs background IRs may negate the need to identify a non-risk period when the risk period is short. This study was for system testing and not to inform regulatory/clinical decisions on pertussis vaccination.

1083 | Characteristics of vaccination errors reported to the European adverse event database EudraVigilance

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Background: Among all post-marketing medication error reports submitted to EudraVigilance, vaccines are the most frequently reported medicinal product. This study aims to describe the characteristics of the medication error reports relating to vaccines.

Objectives: This study aims to describe the characteristics of the medication error reports relating to vaccines.

Methods: EudraVigilance is a spontaneous reporting database for adverse events. We extracted Individual Case Safety Reports (ICSRs) submitted to EudraVigilance between 1 January 2001 and 31 December 2016. Reports were included for analysis if (1) a vaccine was reported as interacting or suspect drug and (2) at least one medication error term was listed as an adverse reaction. ICSRs were stratified by age and gender of the patient, by year of reporting, region of origin (EU/non-EU), reporter profession (Healthcare professional/non-healthcare professional), seriousness of outcome, ATC, and type of medication error.

Results: In total, 7097 ICSRs were included in the study. We observed a yearly increase in the reporting of medication errors with vaccines. The majority of reports was classified as serious, but non-serious reports were increasingly reported since 2012. The mean age of patients was 24.1 years old. The most frequently reported vaccines were influenza vaccines (13.5%), bacterial and viral vaccines combined (12.3%), and hepatitis vaccines (11.8%). A total of 8167 medication error terms were reported. The most frequently reported terms were "Inappropriate schedule of drug administration" (27.2%), "Incorrect route of drug administration" (12.5%), and "Drug administered to patient of inappropriate age" (10.0%). Both the medication error term as well as the vaccine reported were dependent on the age category of the patient. For infants and children, the medication error "Drug administered to inappropriate age" was reported more often than for all other age categories.

Conclusions: Vaccination errors are increasingly reported to EudraVigilance, with characteristics deviating from general medication errors. Based on our results, it is recommendable to analyse vaccination errors separately from other drugs, as well as develop specific measures to prevent errors in this medicinal group.

1084 | Pilot study to assess research capacity for malaria vaccine pharmacovigilance in Ghana and Kenya

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Background: The RTS,S vaccine for malaria prevention was prequalified for use in Kenya and Ghana. Identified and potential adverse events following immunization (AEFI) of interest for this vaccine include febrile convulsions and meningitis. Diagnosis and reporting of AEFI are necessary for vaccine safety surveillance.

Objectives: The goal of this pilot study was to assess the capacity and ability to conduct post-licensure vaccine benefit-risk monitoring of RTS,S in 2 districts in Ghana within the Navrongo Health Research Centre (NHRC) Health Demographic Surveillance Site (HDSS) and 3 districts in Kenya within the Kenya Medical Research Institute (KEMRI)/Centers for Disease Control and Prevention (CDC) HDSS. The objectives were to understand how information on population demographics, vaccine exposure, and potential AEFI of interest are identified, collected, and reported, to evaluate if the available data allows post-licensure vaccine benefit-risk monitoring, and to identify gaps and make recommendations for system improvement.

Methods: Key informant interviews were conducted with community health nurses, malaria health officers, clinicians, data collectors, and data analysts at health facilities at both HDSSs using open-ended questionnaires in January 2018.

Results: In the NHRC study area, 30 interviews were conducted at 21 health facilities. At KEMRI/CDC, 42 interviews were conducted at 13 health facilities. Health facilities in all districts surveyed record child immunization data in paper booklets kept by parents and in a master register maintained at the health facility. Validation of the health care practitioners' diagnoses of the potential outcomes of interest showed inconsistencies with the Brighton Collaboration case definitions and