

ADRs were 55%, non-signals 32%, KUR 4% and potential signals 9%. After grouping similar ADRs and drugs, eleven potential signals underwent in-depth clinical evaluation. This resulted in two non-signals, one KUR and eight signals that will be communicated within the WHO Programme for International Drug Monitoring. Five signals described new suspected ADRs and three described new aspects for previously known ADRs, e.g. regarding severity and previously inadequately described adverse reactions.

Conclusions: Patient reports were a valuable resource in global signal detection and highlighted new suspected ADRs as well as important additional information about already known ADRs.

525. Characteristics and Quality of Spontaneous ADR Reports Submitted via the WEB-RADR App

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Background: Spontaneous reporting of suspected ADRs is key for efficient post-marketing safety surveillance. However, existing reporting tools are sometimes perceived as complex or inaccessible. As a complement, the WEB-RADR consortium developed a mobile phone app based on a simplified reporting form.

Objectives: To evaluate the characteristics and quality of reports submitted via the WEB-RADR app.

Methods: The app was launched in UK in July 2015, Netherlands in January 2016, and Croatia in May 2016. This study includes reports submitted up to September 2016 that (i) were spontaneous, (ii) had a single notifier, and (iii) were submitted directly by a health care professional or patient. For each country separately, the app reports were compared to a set of reference reports, submitted via conventional means during the same period, and meeting the inclusion criteria. The following report characteristics were analysed: the proportions of patient reports and reports concerning females (chi-squared tests), and the median

patient age (Mann–Whitney U test). In addition, a set of 100 app reports and 100 reference reports (for Croatia 37 and 68 reports, respectively) was randomly sampled, stratified by the proportion of patient reports among the app reports. Blinded assessors scored the quality of reports in this subset using a tool called ClinDoc, and the proportion of reports of at least moderate quality was compared (chi-squared test).

Results: A significantly higher proportion of app reports were submitted by patients in UK (28% vs 18%; $p < 0.01$) and Croatia (32% vs 7%; $p < 0.01$), whereas in the Netherlands the difference was small (60% vs 57%; $p = 0.5$). The proportion of female patients among app reports was relatively similar to the reference group, in all countries: 53% vs 60% in UK; 59% vs 64% in the Netherlands; and 76% vs 66% in Croatia ($p > 0.1$ for all). Median patient ages were also similar: 60 vs 55 years in UK; 48 vs 48 years in the Netherlands and 56 vs 56 years in Croatia ($p > 0.05$ for all). The proportion of reports of at least moderate quality was high in both groups, for all countries, but relatively lower for app reports: 83% vs 92% in UK ($p = 0.08$); 85% vs 98% in the Netherlands ($p < 0.01$); and 78% vs 78% in Croatia ($p = 1.0$).

Conclusions: The WEB-RADR app offers a new complementary route of spontaneous reporting that has been shown to attract patients and that could become an important tool in the future. Patient demographics are similar to conventional reporting routes, and report quality is sufficient despite a simplified reporting form.

526. Medication Error Reporting in European Regulatory Database EudraVigilance: A Descriptive Study

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Background: Medication errors are the most common preventable cause of adverse events in health care and a major public-health burden. It is essential to understand the causes, contributing factors and consequences of medication errors. EudraVigilance (EV) is a large database collecting individual case safety reports (ICSR) worldwide resulting in a large dataset from which much information can be obtained. The EU pharmacovigilance legislation (2012) provides a clear legal framework for sharing data on medication errors causing harm.